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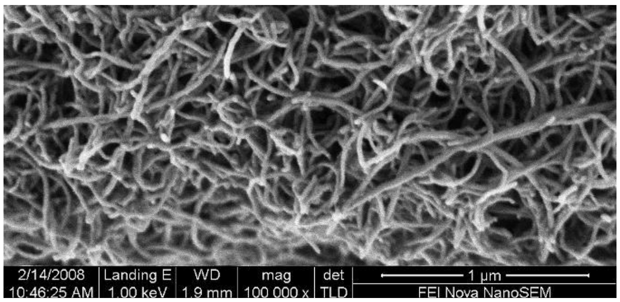
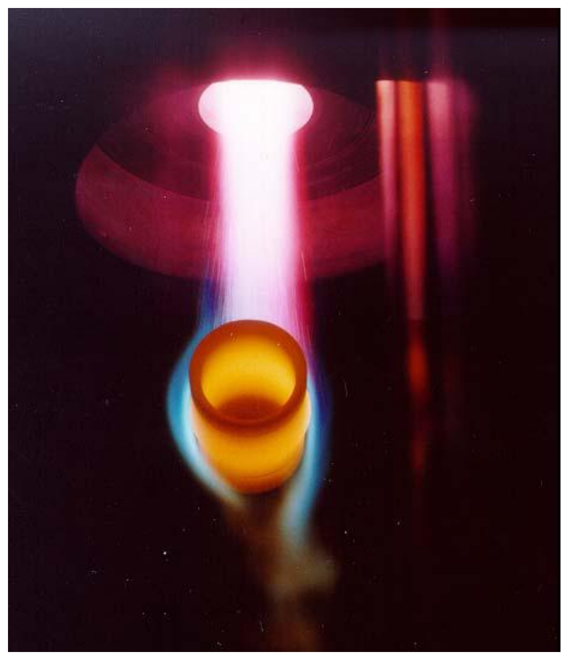
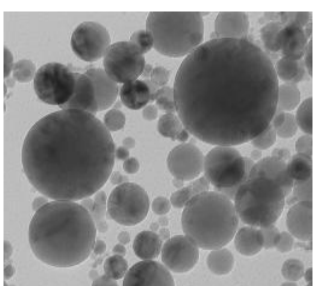
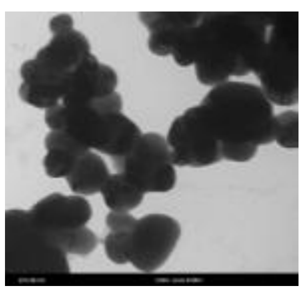
AEPI Report

Managing the Life Cycle Risks of Nanomaterials









July 2009

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Arlington, Virginia 22202-4144
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Office of the Director
(703) 604-2305

The images on the cover show three nanomaterials, two production technologies, and an application.

<u>Top Left</u>
Carbon nanotubes used as source material for studies conducted by U.S. Army Engineer Research and Development Center (U.S. Army ERDC). Image obtained from briefing given by Dr. Jeffery Steevens (U.S. Army ERDC) at the April 2009 National Defense Center for Energy and Environment Program Review.

<u>Middle Left</u>
Induction plasma technology used at Picatinny Arsenal to produce nanomaterials. Photo obtained from briefing given by Mr. Ryan Carpenter, U.S. Army Armament Research, Development and Engineering Center at February 2009 U.S. Army Corrosion Summit.

<u>Bottom Left</u>
Nanoscale aluminum oxide used as source material for studies conducted by U.S. Army ERDC. Image obtained from briefing given by Dr. Jeffery Steevens (U.S. Army ERDC) at the April 2009 National Defense Center for Energy and Environment Program Review.

<u>Middle Left</u>
Transmission electron microscopy image of nanosilver. Image provided by Mr. Alan Kennedy (U.S. Army ERDC).

<u>Top Right</u>
Optoelectronic fiber-device covering (with initial focus on helmet) for combat identification and line-of-sight infrared communications. Photo obtained from briefing given by Dr. John Joannopoulos (Institute for Soldier Nanotechnologies) at the February 2009 Association of the United States Army Annual Meeting and Exposition.

<u>Bottom Right</u>
Vacuum plasma spray deposition technology used to apply nanostructured coatings. Photo obtained from briefing given by Mr. Ryan Carpenter (U.S. Army ARDEC) at February 2009 U.S. Army Corrosion Summit.

REPORT DOCUMENTATION PAGE

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13. ABSTRACT *(Maximum 200 words)*

The Department of Defense (DoD) nanotechnology research, development, test & evaluation (RDT&E) programs are exploiting unique properties found at the nanoscale to enhance war fighter and battle systems capabilities. These advances are expected to deliver beneficial technologies for military as well as human health, environmental, commercial, and industrial applications. However, unique properties and behavior found at the nanoscale may also introduce new risks. This report provides the Army with recommendations for evaluating and managing the potential life cycle risks of nanomaterials. The discussions and recommendations are intended to help the Army understand and minimize nanotechnology-related risks and liabilities while also maximizing opportunities associated with using nanomaterials. Since there are numerous nanomaterial types and variations that are likely to have both military and commercial applications, the discussion and recommendations are relevant not only to the Army, but also to the other Services and commercial users.

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Preface

This report was prepared under contract for the Army Environmental Policy Institute (AEPI) by the National Defense Center for Energy and Environment (NDCEE), operated by Concurrent Technologies Corporation (*CTC*). It discusses specific efforts conducted under Contract Number W74V8H-04-D-0005, Task Number 0520, "Life Cycle Report on Use of Nano-Materials." This report provides the Army with recommendations for evaluating and managing the potential life cycle risks of nanomaterials. As a foundation, the ESOH state of the science, regulatory landscape, risks and liabilities across Army weapon systems and facility life cycles, and approaches for evaluating and managing the risks of nanomaterials are discussed. The discussions and recommendations are intended to help the Army understand and minimize nanotechnology-related risks and liabilities while maximizing opportunities associated with using nanomaterials. Since there are numerous nanomaterial types and variations that are likely to have both military and commercial applications, the discussion and recommendations are relevant not only to the Army, but also to the other Services and commercial users.

The views expressed do not necessarily reflect the official policy or position of the Department of Defense, Department of the Army, or the United States Government.

The mission of AEPI is to assist the Army Secretariat in developing forward-looking policies and strategies to address environmental issues that may have significant future impacts on the Army. In the execution of this mission, AEPI is further tasked with identifying and assessing the potential impacts on the Army of emerging environmental issues and trends.

Please direct comments pertaining to this report to:
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List of Acronyms

µg	microgram
AEPI	Army Environmental Policy Institute
AR	Army Regulation
ARL	Army Research Laboratory
ARO	Army Research Office
ASTM	American Society for Testing and Materials
Cal/EPA	California Environmental Protection Agency
CEA	Comprehensive Environmental Assessment
CFR	Code of Federal Regulations
CMRM	Chemical and Material Risk Management
CNSE	College of Nanoscale Science and Engineering
CRM	Composite Risk Management
DA PAM	Department of Army Pamphlet
DASA-ESOH	Deputy Assistant Secretary of the Army for Environment, Safety and Occupational Health
DoD	Department of Defense
DoDI	Department of Defense Instruction
DOE	Department of Energy
ECOS	Environmental Council of the States
ED	Environmental Defense
EHS	Environment, Health and Safety
EINECS	European Inventory of Existing Commercial Chemical Substances
ENP	Engineered Nanoparticle
ERDC	Engineer Research and Development Center
ESOH	Environment, Safety and Occupational Health
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FY	Fiscal Year
HAZOP	Hazard and Operability
HCP	Health and Comfort Pack
HEPA	High Efficiency Particulate Air
ICON	International Council on Nanotechnology
ILSI	International Life Sciences Institute
IOM	Institute of Occupational Medicine
IR	Infrared
ISO	International Organization for Standardization
ISN	Institute for Soldier Nanotechnologies
LCA	Life Cycle Assessment
LCCA	Life Cycle Cost Analysis
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Assessment
LCRA	Life Cycle Risk Assessment
mg	milligram
MIL-STD	Military Standard
MIT	Massachusetts Institute of Technology
mL	milliliter
MRE	Meal, Ready to Eat
MSDS	Material Safety Data Sheet
MTBE	Methyl Tertiary Butyl Ether
NDCEE	National Defense Center for Energy and Environment
NEHI WG	Interagency Nanotechnology Environmental and Health Implications Working Group
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health

NIST	National Institute of Standards and Technology
NMSP	Nanoscale Materials Stewardship Program
NNI	National Nanotechnology Initiative
NSET	Nanoscale Science, Engineering and Technology
NSF	National Science Foundation
NSTC	National Science and Technology Council
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
OSHAct	Occupational Safety and Health Act
OSTP	Office of Science and Technology Policy
PCA	Program Component Area
PCE	tetrachloroethylene
PEN	Project on Emerging Nanotechnologies
PM	Program Manager
PPE	Personal Protective Equipment
R&D	Research and Development
RDT&E	Research, Development, Test & Evaluation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances
S&H	Safety and Health
TCE	trichloroethylene
TSCA	Toxic Substances Control Act
U.S.	United States
USACHPPM	United States Army Center for Health Promotion and Preventive Medicine
USEPA	United States Environmental Protection Agency
WG	Working Group
WINGS	Web-Interface Nanotechnology Environmental Safety and Health Guidance System

Executive Summary

The Department of Defense (DoD) nanotechnology research, development, test and evaluation programs exploit unique properties found at the nanoscale to advance war fighter and battle systems capabilities. These advances are expected to deliver technologies that benefit human health and the environment through military, commercial, and industrial applications. However, the unique properties of materials at the nanoscale may also introduce risks to human health and the environment.

Proactive assessment and management of potential environment, safety and occupational health (ESOH) risks will ensure the benefits of nanotechnology are realized, safely. To this end, the Army Environmental Policy Institute tasked the National Defense Center for Energy and Environment to summarize nanomaterial efforts within the DoD, identify nanomaterial risks to human health and the environment, review current and emerging nanotechnology-related legislation and policies, and determine approaches for managing the life cycle risks of nanomaterials.

The unique properties, structures, and chemistries of nanoscale materials raise concern that traditional risk assessment and management models and characterization techniques may be inadequate in quantifying ESOH risks. For example, Army system safety frameworks are effective at identifying and reducing or eliminating unacceptable risks from known hazards yet, the hazards associated with most nanomaterials remain unknown. To address this concern, the National Nanotechnology Initiative organized an ESOH research strategy focusing attention on adverse effects to human health and the environment. In addition, Federal and international lawmakers are considering approaches to regulating the safe use of nanomaterials through existing frameworks. However, the current level of ESOH-related research and the application of existing ESOH-related regulations lag behind nanomaterial research and development efforts for military, commercial, and industrial applications.

Although comprehensive risk assessment and management strategies and policies are still emerging, sufficient information is available to develop interim safe working practices to reduce workplace exposures at Army installations where nanomaterials are created, used, or otherwise managed. It is recommended that the Army adhere to published guidelines and best practices based on current ESOH nanomaterial risk research specifically, the March 2009 National Institute for Occupational Safety and Health (NIOSH) guidelines which address safe use and handling of nanomaterials in the workplace.

Good nanomaterial stewardship will require a commitment to identifying and managing ESOH risks throughout the life cycle. The NIOSH guidelines and the Army system safety framework are only stepping-stones to developing robust guidance that ensures identification of potential ESOH risks and impacts during use, scientific uncertainties, control strategies, stakeholders, and risk communication methods. It is recommended that the Army develop a life cycle risk framework that supplements and works in conjunction with existing Army risk frameworks to more effectively consider ESOH risks and impacts of nanomaterials.

To accomplish these recommendations, the Army will need to increase collaborative efforts with ESOH leaders in the DoD, the Federal government, and international agencies. This may include a written agreement, e.g., a memorandum of understanding, with NIOSH or the United States (U.S.) Environmental Protection Agency to ensure appointed Army personnel are empowered to coordinate and collaborate with these agencies.

AEPI Report:
Life Cycle Report on Use of Nano-Materials
Draft Managing the Life Cycle Risks of Nanomaterials Report

1 Introduction

1.1 Purpose of This Report

The purpose of this report is to provide the Army Environmental Policy Institute (AEPI) and the Deputy Assistant Secretary of the Army for Environment, Safety and Occupational Health (DASA-ESOH) with recommendations for evaluating and managing the potential life cycle risks of nanomaterials. The nanomaterial Environment, Safety and Occupational Health (ESOH) state of the science and regulatory landscape are discussed. Methods currently used to manage the life cycle risks of Army systems are compared to proposed approaches for evaluating and managing the life cycle risks of nanomaterials. Recommendations are provided to help the Army understand and minimize risks and liabilities while also maximizing opportunities associated with using nanomaterials. Since numerous nanomaterial types and variations are likely to have both military and commercial applications, the discussion and recommendations are relevant not only to the Army, but also to the other Services and commercial users.

1.2 Background

1.2.1 Nanotechnology

Nanotechnology is the understanding and control of matter that has at least one dimension less than 100 nanometers. Matter in these dimensions displays novel properties differing from single atoms, molecules, and bulk materials. It is an emergent field at the convergence of chemistry, physics, and engineering.

For the purposes of this report, nanotechnology is the engineered formation of passive nanoscale structures such as nanoparticles, nanotubes, nanospheres, and other nano-structured materials (nanomaterials). Several international efforts, including those listed in Figure 1, are underway to develop and define nano-related terms and nomenclature. Formation of nanomaterials requires either top-down or bottom-up production methods. Specifically, top-down methods reduce macro-scale materials to the nanoscale by grinding, etching, spinning, or milling. Bottom-up methods begin with atoms or molecules and use vapor-phase, liquid-phase, and self-assembly techniques to build nanoscale materials.

Agglomerates and aggregates are considered nano-structured materials and may exhibit behaviors and effects similar to their smaller

Existing

ISO/TS 27687:2008 Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate

BSI Publicly Available Specification 71: 2005 Vocabulary. Nanoparticles

ASTM E 2456 - 06 Standard Terminology Relating to Nanotechnology

Under Development

ISO/CD TR 80004-1 Nanotechnologies - Terminology and definitions – Framework

ISO/AWI TS 80004-2 Nanotechnologies -- Terminology and definitions - -- Part 2: Core terms

ISO/CD TS 80004-4 Nanotechnologies - Terminology and definitions -- Part 4: Carbon nano-objects

ISO/AWI TS 80004-5 Nanotechnologies -- Terminology and definitions -- Part 5: Nanostructured materials

ISO/AWI TS 80004-6 Nanotechnologies -- Terminology and definitions -- Part 6: Bio/nano interface

ISO/AWI 80004-7 Nanotechnologies -- Terminology and definitions -- Part 7: Nanoscale measurement and instrumentation

ISO/AWI TS 80004-8 Nanotechnologies - Terminology and definitions -- Part 8: Medical, health and personal care applications

ISO/NP TS 80004-9 Nanotechnologies - Terminology and definitions -- Part 9: Nanomanufacturing processes

Figure 1. Examples of Terminology and Nomenclature Standards

subunits. The term agglomerate refers to accumulations of particles held together by forces of attraction (e.g., hydrogen bonds) and the term aggregate describes clusters of particles held together by strong chemical bonds (e.g., covalent and ionic bonds).

The National Nanotechnology Initiative (NNI) defines nanotechnology as research and technology development at the atomic, molecular, or macromolecular levels in the length scale of approximately 1 to 100 nanometers; and creation and use of structures, devices, and systems with novel properties and functions because of their small size.[1]

This report concerns anthropogenic engineered nano-sized particles. It does not address naturally-occurring nano-sized particles, such as those generated in forest fires or in volcanic ash, nor does it address anthropogenic incidental nano-sized particles, such as welding fumes or combustion byproducts.

1.2.2 Army's Interest in Nanotechnology

Department of Defense (DoD) nanotechnology research, development, test and evaluation (RDT&E) programs aim to advance our understanding of and ability to control matter at dimensions where bulk physical, chemical, and biological properties differ from those of individual atoms, molecules, or bulk matter and exploit these unique proprieties to enhance war fighter and battle systems capabilities.[2] The resulting technologies are expected to deliver benefits that can be applied to military as well as human health, environmental, commercial, and industrial applications.

DoD nanotechnology efforts are aligned with the NNI program component areas (PCAs), with financial investments in seven of the eights PCAs (see Figure 2). The primary emphasis is Fundamental Nanoscale Phenomena and Processes, Nanomaterials, and Nanoscale Devices and Systems. No investments have been made in the Education and Societal Dimensions PCA. Additional detail about the activities of the Defense Nanotechnology Research and Development Program can be obtained from annual reports prepared since 2005.[3]

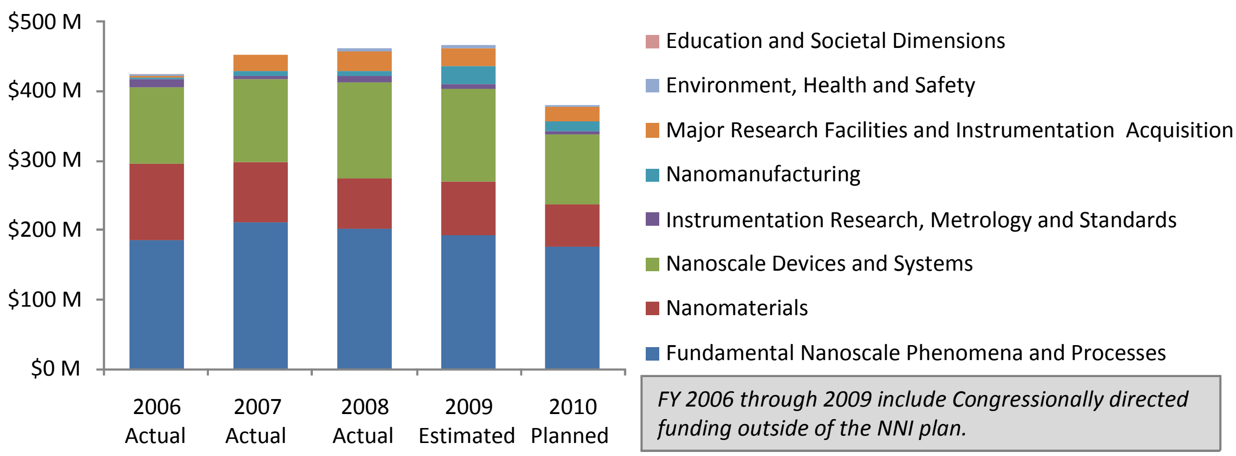

Figure 2. DoD Investments in Nanotechnology by Program Component Area[4]

The Army is responsible for roughly 15% of the Defense Nanotechnology Research and Development Program investments. This includes a collection of individual efforts focused on diverse aspects and applications of nanotechnology and occurring in a variety of program elements within the Army's RDT&E

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[1] For the NNI's definition of nanotechnology, see http://www.nano.gov/html/facts/whatIsNano.html
[2] Department of Defense (2007)
[3] Department of Defense (2005, 2006, 2007); Porter (2008)
[4] National Science and Technology Council (2008c, 2009)

budget. While most of these efforts are in the RDT&E categories 6.1 (basic research) and 6.2 (applied research), some nanotechnologies have transitioned to the development or demonstration stage. For example, Meals Ready to Eat (MRE) bags fabricated from a low density polyethylene nanocomposite are in RDT&E category 6.3 (advanced technology development).[5]

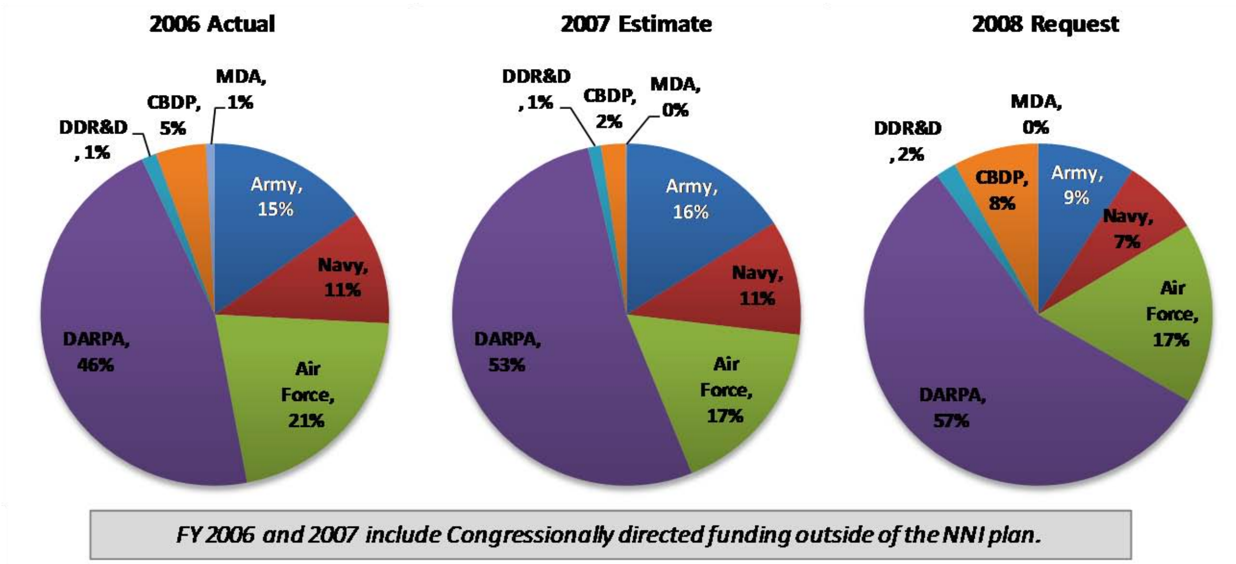

Figure 3. DoD Nanotechnology Investment by Agency[6]

Table 1 lists Army-funded example centers where unclassified RDT&E nanotechnology projects take place and Table 2 identifies unclassified items with the descriptor "nano" from the Army's fiscal year (FY) 2009 RDT&E budgets estimates.[7] These examples illustrate the breadth and variety of research projects, representing a range of scientific disciplines, states of development, types of nanotechnology, and anticipated applications. What they share in common is the potential for ESOH risks throughout the technology's life cycle.

[5] Department of the Army (2008c)
[6] Department of Defense (2007)
[7] Department of the Army (2008c)

Table 1. Examples of Unclassified Army-Funded Nanotechnology RDT&E Centers

Name	Description	Objectives
Center for National Nanotechnology Innovation & Commercialization[8]	Research partnership between the United States (U.S.) Army Research Laboratory (ARL) and the University of Albany's College of Nanoscale Science and Engineering (CNSE)	Develop and demonstrate next-generation devices, structures and systems to support combat operations and enhance protection of its troops
Institute for Soldier Nanotechnologies (ISN)[9]	Interdepartmental research center at the Massachusetts Institute of Technology (MIT) funded by the U.S. Army Research Office (ARO)	Develop and exploit nanotechnology to dramatically improve the survivability of Soldiers and help the Army create a 21st century battlesuit that combines high-tech capabilities of light weight and comfort
Nanoelectronics Laboratory	Research laboratory at the University of Cincinnati with sponsorship from the ARO as well as others.	Develop low-power nanoscale sensor and communication devices suitable for individual combatant protection and novel survivability[10]
Nanoparticle Reactor Facility at Picatinny Arsenal[11]	Dual use military and commercial facility funded via a public-private partnership	Synthesize, process, and characterize nanophase and nano-structured materials, fully dense near-net shape bulk components, and nano-structured coatings
Natick Soldier Research, Development, and Engineering Center[12]	Dedicated Army RDT&E Center which reaches a broader audience through technology transfer and cooperative agreements with private industry and other government agencies	Maximize the Warrior's survivability, sustainability, mobility, combat effectiveness and quality of life by treating the Soldier as a system
U.S. Army Engineer Research and Development Center (ERDC) Nanomaterials Research Cluster[13]	Interdisciplinary team of experts in the fields of material science, geology, soil science, toxicology, and computational chemistry	Understand the unique environmental attributes of nanomaterials and assist nanotechnology developers while balancing the environmental risks

[8] See http://cnse.albany.edu/business_resources/centers_programs/NNICC.html
[9] See http://web.mit.edu/isn/
[10] Department of Defense (2007) and http://www.nanolab.uc.edu
[11] Carpenter (2009)
[12] See http://nsrdec.natick.army.mil/about/index.htm
[13] See http://el.erdc.usace.army.mil/nano/

Table 2. Examples of Unclassified "Nano" Applications Listed for Army FY2009[14]

RDT&E Category		Examples of Listed "Nano" Items
6.1	Basic Research	Environmentally-responsive hydrogels for nanomaterial synthesis and biomimetic material nanosensory devices for biological or chemical detection
6.2	Applied Research	Energetics, made from nanoscale structures, that have minimal environmental waste, long storage lifetime, and rapid environmental degradation
6.3	Advanced Technology Development	MRE meal bags fabricated from a low density polyethylene nanocomposite
	System Development and Demonstration	Enhanced capabilities and durability of tactical and non-tactical clothing through use of nanotechnology

In addition to items funded by DoD, nanotechnology-based products developed by the private sector are being marketed to and may be purchased and used by the military. For example, Health and Comfort Packs (HCP) distributed to forward area troops include non-food necessities, including sunscreen.[15] The type of sunscreen is not specified, but many sunscreens now contain nanoparticles of titanium dioxide or zinc oxide. Nanosilver, which is incorporated in approximately 20 percent of the products listed in the Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies (PEN) consumer products inventory,[16] is found in wound dressings, socks, and soap. Lack of labeling requirements makes it difficult to know if the Army is procuring products containing nanomaterials.

1.2.3 Environment, Safety and Occupational Health Concerns

The major source of concern regarding the potential ESOH risks of nanotechnology are those nano-sized particles that are not attached to a surface or are not part of a bigger item and can thus be transmitted via air, water (or other liquid or viscous medium), soil, vegetation, or biota, resulting in potential exposure via inhalation, ingestion, dermal, or ocular routes. Adverse health effects in receptor populations may include inflammation, oxidant stress, fibrosis, or genetic translocation.

In March 2009, the Institute of Occupational Medicine (IOM) published its EMERGNANO paper, which reported results from a meta-analysis of international reviews considering nanomaterial risks. The IOM concluded that there are potential ESOH risks from the manufacture and use of nanomaterials, there is a lack of knowledge about the nature and magnitude of these risks, the potential for exposure to humans and the environment is directly correlated with the development of nanomaterial processes and products, and stakeholders need to address these risks immediately.[17]

It is becoming increasingly important for the Army to proactively manage the risks of its operations. Nanomaterials may pose new ESOH risks. Regulators, including the U.S. Environmental Protection Agency (USEPA), the U.S. Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA), are considering the most appropriate approaches to regulate engineered nanomaterials. As a result, their use may be controlled or restricted. Understanding of the ESOH risks lags behind nanomaterial research and development (R&D). Failure to consider risks during R&D, testing, production, and acquisition may lead to unanticipated and costly consequences.

1.2.4 Army Sustainability Perspective

The vision of the Army Strategy for the Environment is to sustain the Army mission while securing resources for future generations. The Army promotes a balanced triple bottom line of sustainability:

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[14] Department of the Army (2008a)
[15] Defense Supply Center Philadelphia (2008)
[16] See http://www.nanotechproject.org/inventories/consumer/
[17] Aitken et al. (2009)

mission, environment, and community. This requires consideration of the life cycle impacts (positive and negative) of emerging technologies being developed for use within the Army.

In 2005, the AEPI published a research paper on the Army's potential use of nanotechnology into the future,[18] portions of which were summarized and included in the November 2005 AEPI Army Foresight publication on Nanotechnology.[19] The paper examined potential societal and defense implications of nanotechnologies on the Army soldier's environment. It discussed broad-based uses of nanotechnology and provided insight as to the best implementation strategy for the Army. This strategy enlisted the support of the public and other stakeholders in the development of nanotechnology for military applications. It also stated that the Army should provide guidance and oversight for the safety and environmental aspects of acquisition processes.

Recommendations for "next steps" made in the 2005 report included continued research on ESOH effects of nanomaterials, identification of the predictable and unintended consequences on public health and the environment from the Army's development and use of nanomaterials, and continued cooperation with stakeholders to develop risk assessment tools and appropriate regulations.[20] These recommendations remain nascent; efforts to incorporate them into current nanomaterial RDT&E practices are still emerging.

2 ESOH State of the Science

Risk is a function of hazard and exposure. Data on toxicity (hazard) and the frequency, intensity, and duration of exposure are required to quantify and qualify potential risks of nanomaterials to human health and the environment. Yet, there is a lack of knowledge and much scientific uncertainty about adverse effects of nanomaterials in humans or the environment and about how to measure such potential exposures.

Unintentional exposure may occur via inhalation, ingestion, dermal, and ocular pathways. Media that may serve as pathways for nanomaterials include air, water (or other liquid or viscous media), soil, vegetation, and biota. Nano-structured materials that may release nano-sized particulate matter into the environment during RDT&E, manufacture, use, or disposal are of concern if the nano-sized contaminants are or can become biologically active. While nanoparticles fixed within a solid medium do not result in exposure to humans or the environment, these particles may be freed from the medium if it is physically or chemically altered. Determining whether a nanomaterial is or can become biologically active depends on various factors including, but not limited to, its size and size distribution, shape, surface area, surface chemistry, porosity, solubility, and ability to agglomerate or aggregate, and factors of the media, such as pH and temperature.

To evaluate worldwide progress in identifying ESOH nanotechnology risks requires a compilation of existing research projects relating to risk assessment and risk management sciences. The IOM's 2009 EMERGNANO report reviewed more than 260 unique, relevant research activities in progress, close to completion, or already completed.[21] The activities consist of international, multidisciplinary research conducted in hazard identification, toxicity and dose response, and exposure assessment. After reviewing these activities, the authors conclude that thus far progress to address environment, health, and safety risks has been "disappointing."[22]

A second literature review, presented at the February 2009 Human and Environmental Exposure Assessment Workshop sponsored by Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC) and the National Institute for

[18] McGuinness (2005)
[19] Army Environmental Policy Institute (2005)
[20] McGuinness (2005)
[21] Aitken et al. (2009)
[22] Aitken et al. (2009)

Occupational Safety and Health (NIOSH), revealed a lack of published articles and funding for ESOH risk research. A thorough review of relevant databases, dating back more than 50 years on topics including engineering controls, workplace and environmental exposure monitoring, and clinical care revealed 154 unique nanotechnology-related articles.[23] Of these, only 27 percent dealt specifically with nanotoxicology and occupational exposure assessment. There were no articles concerning exposure registries, adverse health outcomes, community exposure assessment, environmental exposure assessment, or morbidity and mortality.

Federal grant opportunities in the pipeline as of February 2008 from National Institutes of Health (NIH), the National Science Foundation (NSF), military and other non-NIH/NSF agencies revealed 56 unique grants having to do with nano-related adverse health outcomes.[24] Of these, only five percent dealt specifically with methods for exposure assessment. The absence of published environment, health, and safety risk research, toxicological research, and epidemiological research reflects the amount of funding allocated to these fields. Without funding, research into these critical areas cannot proceed.

To address the data gaps and move forward with identifying funding priorities, the NNI organized a risk research strategy for nanotechnology-related research. In 2008, the NNI outlined a strategy based on priority Environment, Health and Safety (EHS) research needs identified earlier in the NNI publication *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*.[25] Five primary research categories have been established for the EHS PCA:

- Instrumentation, metrology and analytical methods
- Nanomaterials and human health
- Nanomaterials and the environment
- Human and environmental exposure assessment
- Risk management methods

Between 2008 and 2010, the Interagency Nanotechnology Environmental and Health Implications Working Group (NEHI WG) is convening workshops addressing each EHS research category. The goals of these workshops are to assess the state of the science and reassess areas of weakness and gaps. Organizers of these workshops include those Federal entities who have been assigned Coordinating Agency status, meaning that these agencies have been designated a primary EHS function for the Federal government. These entities include: National Institute of Standards and Technology (NIST), NIH, USEPA, FDA, and NIOSH.[26]

The DoD is not a Coordinating Agency for EHS risk research. Instead, the DoD has two EHS-related roles, one as a user of the research output to support its mission and the other as a contributor of funding for EHS risk research. The DoD has contributed funding or is planning to fund research in two of the five EHS categories: nanomaterials and the environment and risk management methods. As a user and contributor, the DoD has a keen interest in participating in NEHI workshops and is a stakeholder in research strategy development and execution. Table 3 identifies the Coordinating Agencies and summarizes DoD's role for each of the EHS PCA's primary research categories.

[23] Halperin and Tashiro (2009)
[24] Halperin and Tashiro (2009)
[25] National Science and Technology Council (2006, 2008a)
[26] National Science and Technology Council (2008a)

Table 3. EHS Primary Research Categories, Workshops, and DoD Involvement

EHS Research Category	Coordinating Agencies	Workshop Status	DoD Participation
Instrumentation, metrology and analytical methods	NIST	Workshops scheduled for October and November 2009[27]	User
Nanomaterials and human health	NIH	Workshop scheduled for November, 2009[28]	User
Nanomaterials and the environment	USEPA	Workshop scheduled for October 2009[29]	Funding support for environmental fate and transport research
Human and environmental exposure assessment	NIOSH	February 2009: Workshop held in Bethesda, MD; results of the Workshop will be used to inform next steps in research strategy[30]	User
Risk management methods	USEPA, FDA	Workshop to be scheduled	Funding support for Web-Interface Nanotechnology Environmental Safety and Health Guidance System (WINGS) development

Investments in EHS research have increased in recent years, it is unclear whether this trend will continue. As illustrated in Figure 4, the EHS PCA investments planned for FY2010 make up the majority of the USEPA and NIOSH total investments, but the minority of NIST and NIH total investments. The pie charts compare the percent of EHS PCA investments with the total investments in the remaining seven NNI PCAs. Of the total planned FY2010 NNI budget investments for the 13 participating agencies, approximately five percent ($88 million out of $1.6 billion) is dedicated to the EHS PCA, more than double the $35 million dedicated to the EHS PCA in FY2005.[31] However, the FY2010 budget value remains an order of magnitude lower than estimates made regarding ideal EHS funding investments. PEN, in their agenda for the new administration, suggested an increase in funding to $150 million [32] and in a 2009 article published in *Environmental Science & Technology*, estimates ranged from $249 million to $1.18 billion. These estimates were made based on a tiered risk assessment strategy that allowed for a range of assumptions about EHS nanomaterial hazards (i.e., optimistic lower-cost assumptions versus precautionary higher-cost assumptions).[33]

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[27] See http://www.nano.gov/html/meetings/environment/ and http://www.nano.gov/html/meetings/humanhealth/ for more information.
[28] See http://www.nano.gov/html/meetings/humanhealth/ for more information.
[29] See http://www.nano.gov/html/meetings/environment/ for more information.
[30] See http://www.nano.gov/html/meetings/exposure/index.html for more information.
[31] National Nanotechnology Initiative, http://www.nano.gov/html/society/EHS.html, Accessed May 12, 2009.
[32] Davies (2008)
[33] Choi et al. (2009)

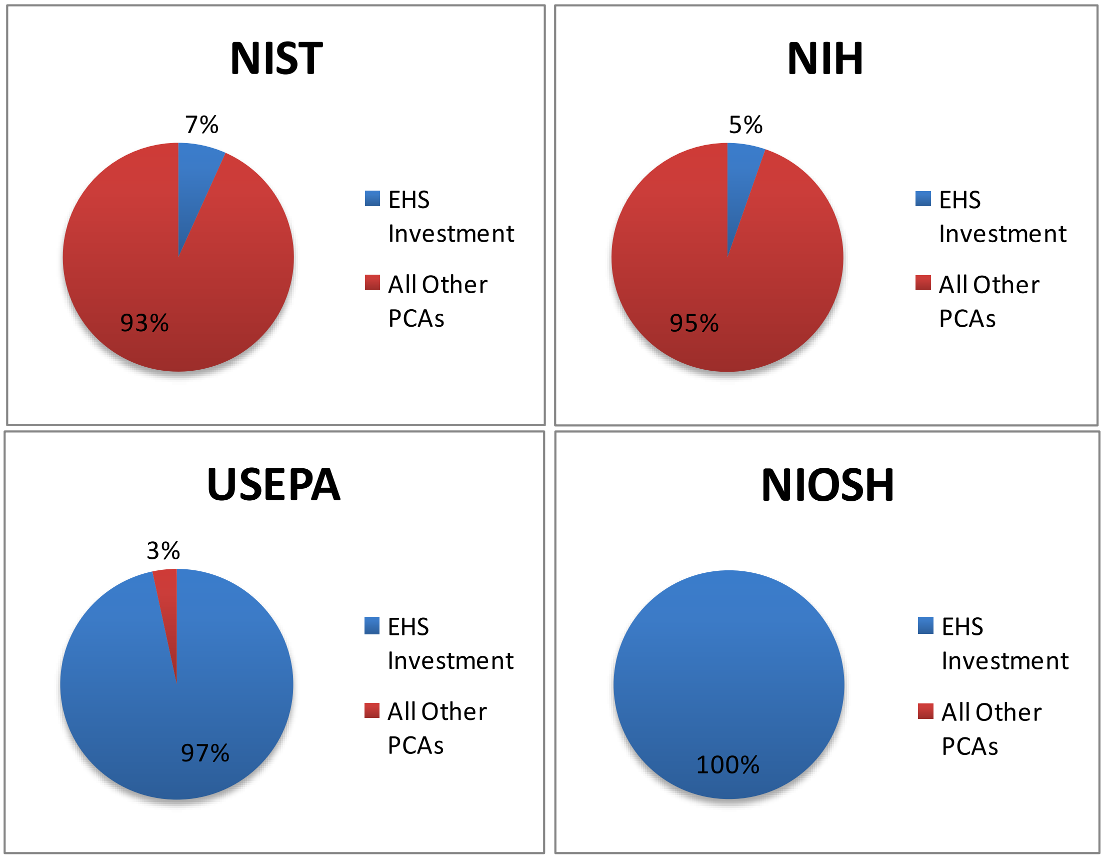

Figure 4. FY2010 EHS Investment Dollars as a Percentage of Total NNI Investments[34]

In the Army and throughout the DoD, a flexible, proactive, tiered risk-based strategy can be implemented to reduce current and future vulnerabilities as well as the resources (financial, technological, or human capital) needed to implement them. To accomplish this, the Army may elect to leverage their resources to effectively address ESOH concerns. In so doing, the Army would achieve the DoD's pledge[35] to coordinate nanotechnology research programs with the Services and Federal agencies (e.g., the Coordinating Agencies for the EHS PCA) and avoid duplication of efforts.

The next sections highlight the evolving state of the science framed around four of the five EHS PCA primary research needs as identified by the NNI. The implications to the Army are discussed.

2.1 Instrumentation, Metrology, and Analytical Methods

The NNI's 2008 strategy for nanotechnology-related EHS research defined the instrumentation, metrology, and analytical methods priority research area as the development of suitable metrics and associated methods for the detection, measurement, and characterization of nanomaterials in the environment, including the workplace; the development of certified reference materials for chemical and physical characterization of nanomaterials; and the development of methods for standardizing assessment of nanomaterial physicochemical properties.[36]

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[34] National Science and Technology Council (2009)
[35] Department of Defense (2007)
[36] NSTC (2008a)

As summarized in the comprehensive 2009 EMERGNANO report, research activities in this priority research area "barely scratch the surface" of what is needed to make informed decisions.[37] The findings from that report include the following:

- Studies focusing on the relevance and practicality of surface area as a guide to characterize and measure nanomaterials are limited in scope and conclusiveness. Air sampling methods and strategies will vary depending on the type of material, the work environment, and the nature of the operation being investigated.
- The need for assessment of explosive properties for many nanomaterials has been repeatedly highlighted in literature, yet the response has been somewhat limited. Nanomaterials may present higher risks than coarser materials of similar quantity and some metals may exhibit an increased risk of explosion as particle size decreases.
- There is slow progress in the development of reference materials. These materials would provide researchers with benchmarks to study, monitor, and potentially track nanomaterials to assess their interactions with different media.

Given these recognized research gaps, Army environmental and occupational health practitioners who monitor potential exposures and releases must rely on existing metrics and methods for the collection and analysis of nanomaterial samples. The goal of nanomaterial sample collection should be to determine, at a minimum, the particle mass, particle number, particle size and size distribution, and surface area. These determinations can be made through gravimetric analyses or, depending on the installation's resources, portable, direct read instruments for particulate readings in the nanometer range. These include light scattering photometers, optical particle counters, condensation particle counters, and surface area particle monitors. Samples can be analyzed using transmission electron or scanning electron microscopy to evaluate morphology or fluorometry and electrophoresis for characterization of nanoparticles. However, much of this equipment is specialized and may not be readily available at all sampling or analysis facilities.

2.2 Nanomaterials and Human Health

The 2008 NNI EHS strategy defined the nanomaterials and human health priority research area to include development of methods to quantify and characterize exposure to nanomaterials; identification of appropriate *in vivo* and *in vitro* models to predict human responses; and assessment of nanomaterial properties that increase body burden.[38]

Inhalation is regarded as the most important exposure route for nanomaterials. Once in the airway, nanomaterials can be distributed in the body and may cross the blood-brain barrier.[39] There are very few *in vivo* studies currently being conducted, making comparison between *in vitro* and *in vivo* data problematic. The 2009 EMERGNANO paper presented these key findings from human health-related studies:

- Research to understand deposition, distribution, toxicity, and pathogenicity, pathways in airways, and potential impacts on various organ systems have been conducted for carbon nanotubes, but few other nanomaterials.
- Dermal uptake is not being addressed, yet it has been determined that it is imperative to understand whether different types of nanomaterials can penetrate the skin and whether dermal uptake can lead to any toxic effects.[40]

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[37] Aitken et al. (2009)
[38] NSTC (2008a)
[39] Swedish Chemicals Agency (2008)
[40] Aitken et al. (2009)

Published research findings indicate human health impacts may occur after exposure to zinc oxide nanoparticles, carbon nanotubes, titanium dioxide, and tungsten carbide cobalt. Table 4 provides an overview of these nanomaterials, potential human health impacts, and their connection with DoD uses.

Table 4. Examples of Potential Human Health Impacts from Select Nanomaterials

Nanomaterial	Example Findings	Example DoD Link
Zinc oxide nanoparticles	A study of human epidermis cells indicates significant damage to DNA from zinc oxide nanoparticles at concentrations of 0.8 micrograms (µg) per milliliter (mL) and 5.0 µg/mL after six hours of exposure. The concentrations studied are much lower than those actually found in sunscreens (average160 milligrams (mg)/mL).[41]	Sunscreens supplied in Health and Comfort Packs may contain zinc oxide nanoparticles
Single-walled carbon nanotubes	Rapid, but transient inflammation in lung tissues with granulomas and fibrosis at deposition sites of agglomerates.[42]	Potential research and development activities using single-walled carbon nanotubes.
Titanium dioxide nanoparticles	Particles triggered release of reactive oxygen species which can cause damage in surrounding cells in the brain.[43]	Used in thermally-sprayed nanocoatings for Navy and civilian applications.[44]
Tungsten carbide cobalt nanoparticles	Demonstrate cytotoxic effects at high particle concentrations. [45]	Used in the manufacture of tools and in thermally-sprayed nanocoatings for both Navy and civilian applications.[46]

In response to findings linking titanium dioxide nanoparticles with potential adverse human health effects, the DoD issued a statement that "the military should begin its own preventive health research and start considering possible replacements for any titanium dioxide nanoparticle-containing products it uses."[47] This action demonstrated the DoD's concern for potential health impacts and recognized the need for further research into safer alternatives. Near-term plans to identify human health risks include the USEPA's National Center for Computational Toxicology's launch of the ToxCast pilot program to use data from high throughput screening bioassays to build computational models intended to predict chemical toxicity.

2.3 Nanomaterials and the Environment

The 2008 NNI EHS strategy identifies the nanomaterials and the environment priority research area to include the identification of principle sources of environmental exposure and exposure routes; evaluation of abiotic and ecosystem-wide effects; determination of factors affecting environmental transport; and impacts of environmental conditions on transformation.[48]

Quantities and concentrations at which nanomaterials may be toxic in the environment are unknown. In addition, the analytical methods for characterizing and detecting nanomaterials in environmental media may not be effective.[49] The comprehensive 2009 EMERGNANO paper concluded the following:

[41] European Commission (2009)
[42] Environmental Health Sciences (2009)
[43] Long et al. (2006)
[44] Inframat® Corporation, http://www.inframat.com/feed.htm, Accessed May 12, 2009
[45] Bastian et al. (2009)
[46] Inframat® Corporation, http://www.inframat.com/feed.htm, Accessed May 12, 2009
[47] Battelle Columbus Operations (2006)
[48] NSTC (2008a)
[49] Linkov et al. (2009)

- Research to date focuses predominantly on aquatic organisms of the oceans or seas; no groundwater or soil exposure scenarios have been studied.
- Studies cover a limited range of species (e.g., specific invertebrates and microorganisms) and material types (e.g., metal oxides and carbon nanotubes); a range of species and a range of nanoparticles need to be studied.[50]

Published research findings indicate environmental health impacts may occur after exposure to quantum dots, carbon nanotubes, and nanosilver. Table 5 provides an overview of the nanomaterials, potential environmental impacts, and their connection with DoD uses.

Table 5. Examples of Potential Environmental Health Impacts from Select Nanomaterials

Nanomaterial	Example Findings	Example DoD Link
Quantum dots	Quantum dots are used in electronics, solar energy generation, and imaging applications. They consist of a heavy metal core coated with organic materials that allow conjugation with biological molecules. Quantum dots are potentially safe materials when used in their intended applications at near-neutral pH. However, moderately acidic or alkaline conditions could lead to significant and localized organism effects due to toxic exposure to dissolved heavy metals.[51]	Cadmium-selenide quantum dot nanoparticles are being investigated to determine bacterial biotransformation occurrence.[52]
Multi-walled carbon nanotubes	Hydroxylated and carboxylated multi-walled carbon nanotubes have different settling rates than nanotubes without functional groups. In addition, agglomeration of nanotubes is affected by the presence of natural organic matter in these media.[53]	U.S. ERDC researchers and their associated research partners are studying environmental risks from multi-walled carbon nanotubes. Nanotubes may be used in a variety of applications, including sealants and fillers.[54]
Nanosilver	Silver nanoparticles (no size stated) were shown to have harmful effects on aquatic invertebrates at low concentrations. [55]	DoD researchers are studying nanosilver's potential for use in a variety of military applications, including the development of photographic film.[56]

These nanomaterials are important to current RDT&E efforts sponsored by the Army and other Services. For example, ERDC researchers in Vicksburg, MS and associated academic research partners focus on ecological health risks and environmental attributes of nanomaterials used in military applications, e.g., multi-walled carbon nanotubes, fullerenes, waste materials from fullerene production, nano-aluminum, and nanosilver. These researchers are working to develop a framework for comparative/relative risk analysis as well as atomic-scale models for predictions based on structure and surface chemistry.

[50] Aitken et al. (2009)
[51] Mahendra et al. (2008)
[52] Crocker (2008)
[53] Kennedy et al (2008)
[54] Department of Defense (2005)
[55] Aitken et al. (2009)
[56] Department of Defense (2005)

2.4 Human and Environmental Exposure Assessment

This EHS priority research area considers the need for information that characterizes nanomaterial exposures among affected populations, e.g., workers and the public. As defined in the NNI's EHS strategy, this research area includes the identification of population groups and environments; characterizing the health of these population groups; and understanding workplace processes and factors that determine exposures.[57]

Several reports identify workers as the population with the greatest potential for exposure to nanomaterials. For example, a European Union report written by 49 experts across Europe ranked nanoparticles first among the list of substances from which workers need protection.[58] Another recent study[59] determined workers are at an increased potential for exposure to nanomaterials when performing the following tasks:

- generating nanoparticles in non-enclosed systems
- handling powders
- working with nanoparticles in liquid suspensions
- pouring or mixing, or where agitation is involved
- machining, sanding, or otherwise mechanically disrupting nanomaterials
- conducting maintenance activities on equipment used to produce nanomaterials
- cleanup of releases or waste and cleanup of dust collection systems

Studies have indicated that engineering controls and personal protective equipment may be effective in preventing or minimizing exposure in the workplace, at least for some nanomaterials, but may vary depending on differences in particle mass and number. Referencing several of these studies, the 2009 EMERGNANO report indicates several control methods are effective, e.g., laboratory fume hoods, high efficiency particulate air (HEPA) filters in respiratory protection and air cleaning systems, and the use of double gloves.[60]

Although comprehensive quantitative exposure assessments are still missing, sufficient information is available to begin preliminary assessment and to develop interim working practices to reduce workplace exposures at Army and other DoD installations where nanomaterials are created, used, or otherwise managed.

3 Nanomaterial Policy and Regulatory Landscape

All 50 states are home to at least one company, university, government laboratory, or other type of organization working with nanomaterials.[61] Investment in nanotechnology is also taking place globally and across industrial sectors, including those that produce inexpensive and clean energy and clean water, reduce pollution, create medical innovations, or develop new materials based on old concepts (e.g., plastics, thin films, and transistors). As already discussed, nanomaterials provide researchers and manufacturers with opportunities to optimize specific physicochemical and surface characteristics that offer unique electrical, thermal, mechanical, and imaging properties. These properties are different from those of their non nano-sized counterparts, thus making them potentially subject to legislation, regulations, and policy guidance concerning novel chemicals and new uses.

[57] National Science and Technology Council (2008a)
[58] European Agency for Safety and Health at Work (2009)
[59] Schulte et al. (2008)
[60] Aitken et al. (2009)
[61] Keiner (2008)

Government intervention to promote environmental health, human health, and safety may take the form of mandatory or voluntary health and safety standards. Mandatory, enforceable standards are regulations published by a regulatory agency that has been authorized by legislation to enforce laws. For example, the Hazard Communication regulation is a standard published by Occupational Safety and Health Administration (OSHA). OSHA has authority to enforce this regulation per the Occupational Safety and Health Act (OSHAct), a law passed by the U.S. Congress. Voluntary health and safety standards include non-enforceable policy instruments such as the International Organization for Standardization (ISO) series on environmental management and are often adopted as best management practices.

In the U.S., the current regulatory frameworks are expected to be sufficiently flexible to cover nanotechnology research, development, manufacturing, and commercialization. However, some scientists and regulators have expressed concern that these laws are not being properly exercised, leaving several nanotechnologies essentially unregulated.[62] In addition, the variety of nanomaterials and diverse applications may challenge these legal frameworks, raising concerns about the need for new frameworks.

Until a Federal-level oversight system addressing life cycle risk management is enacted into law or is adopted by existing Federal agencies under their present authorities, there is room for others to move forward into the oversight arena. Potential actions to fill gaps in Federal oversight may include initiatives at the international, State, and local government level, and through collaborative efforts of industry, academia, and government. These initiatives favor precaution, yet lend to a mismatch in regulatory and policy guidance schemes.

For example, to thwart liability arguments, investment firms have proposed shareholder resolutions aimed at specific companies manufacturing nano-enabled products. The resolutions encourage amendment of the company's product safety policies to include activities on labeling, consumer education, and options for selections of alternative materials.[63] Such resolutions encourage attention to product stewardship, yet are not necessarily consistent from company to company or product to product. With the initiation of various policy instruments by various stakeholders, nanotechnology researchers and developers are left to maneuver through a patchwork of guidance. The following discussion highlights the current regulatory and policy landscape.

3.1 Federal Oversight

During the 110th Congress, at least 20 bills related to nanotechnology were introduced. The majority of these bills concerned stimulating research and development of nanotechnology and nanotechnology industries rather than research or action to address potential ESOH risks throughout the life cycle. As of April 2009, three nanotechnology-related bills have been introduced into the 111th Congress, two into the House of Representatives (H.R. 554 and H.R. 820) and one into the Senate (S. 596).

H.R. 554, the National Nanotechnology Initiative Amendments Act of 2009, would reauthorize NNI activities for support of nanotechnology research and development. The bill, referred to the Senate Committee on Commerce, Science, and Transportation in February, 2009, will require coordination of ESOH research through a senior official in the White House Office of Science and Technology Policy (OSTP), instead of through NSET. In addition to this change, the Act would require a research plan for ESOH research activities that could be tracked in a publicly-accessible database.

The remaining two bills, H.R. 820 and S. 596, concern research and development of nanotechnology. Although these bills do not address ESOH risks, the fact that three nanotechnology-related bills have been introduced within the first four months of the new Congress indicates a trend towards increased legislative activity.

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[62] Davies (2008), Sass et al. (2008)
[63] Investor Environmental Health Network (2008)

In addition to new legislation governing nanotechnology, it is possible that changes to existing laws governing environmental health and worker safety may be proposed within the next two years. Initiatives to update or change existing laws are driven by changes in science and changes in political and legislative agendas. The law receiving the most attention from stakeholders and policymakers is the Toxic Substances Control Act (TSCA), enforced by the USEPA. TSCA is being challenged by proposed legislation such as the Kid-Safe Chemicals Act and international regulations such as the European Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) regulation. No timeframe has been established, but revisions to TSCA could have far-reaching implications on how chemicals and substances are defined and regulated, including, but not limited to, nanomaterials.

The USEPA is authorized to enforce TSCA, as well as the Clean Air Act, Clean Water Act, Comprehensive Environmental Response, Compensation, and Liability Act, Resource Conservation and Recovery Act, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) -- all of which govern the USEPA's authority to regulate hazardous substances and promote human health and the environment. These regulations are part of the existing Federal framework of environmental regulations which may be sufficiently flexible to cover nanotechnologies. Yet, one of the hindrances to applying these regulations to nanomaterials is that the USEPA bears the burden of showing proof of harm and evidence of potential human health and environmental risks. The USEPA has been pressed by industry to make nanomaterial-related regulatory determinations based on sound science. However, the lack of significant human health and environmental toxicity data has placed policymakers in a position where they must decide whether to regulate absent evidence of harm or not regulate until further risk information becomes available.

The purpose of TSCA is to regulate commerce and protect human health and the environment by gathering health and safety information about chemical substances and controlling, as needed, those deemed hazardous. In order to gather existing toxicity information on nanomaterials, the USEPA must consider the material be "new" or to have a significant new use. A chemical is new only if its molecular identity differs from that of substances already listed in TSCA's existing chemical inventory. A chemical that is not new but is a new use of a material already recognized on the TSCA inventory is categorized as having a significant new use. To date, only two types of nanomaterials, carbon nanotubes and fullerenes have been classified as new or significant new use chemicals. This means that companies who intend to manufacture or import these nanomaterials are required to submit a premanufacture notice to the USEPA at least 90 days to the activity.

The other USEPA laws previously mentioned have yet to be applied to nanomaterials, with one exception, FIFRA. Under FIFRA, the USEPA regulates those substances intended to prevent, destroy, repel, or mitigate pests. The USEPA already regulates silver as an active ingredient in registered pesticides and it has taken its first step in acquiring information on the use of nanosilver as a pesticide. The USEPA will consider future regulation of nanotechnology-enabled pesticides in the coming months as it collects and considers comments solicited in a November 2008 Federal Register notice.[64] Silver nanoparticles are currently used in products on the market, including nanosilver containing clothing articles and cosmetics.

To encourage participation in the development of health and safety-related data, the USEPA launched the voluntary Nanoscale Materials Stewardship Program (NMSP) in January 2008. The initiative asks every commercial firm and research organization manufacturing, purchasing, processing, or otherwise using nanomaterials to submit information concerning their material's chemical and physical properties, hazard information including any health or safety studies, the extent of worker or other human exposure throughout its expected life cycle, the nature and extent of any releases, and risk management practices in use. These data would be used to provide a foundation for regulatory decisions concerning nanomaterial ESOH issues.

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[64] United States Environmental Protection Agency (2008)

As of January 2009, 29 companies or groups voluntarily submitted information covering more than 123 nanoscale materials to the NMSP.[65] Two-thirds of commercially-available chemicals and 90% of nanomaterials were not reported.[66] The data collected as of that time leaves the USEPA with a number of ESOH data gaps, i.e., there is uncertainty whether submitters provided data on all nanomaterials they produce. In response, the USEPA will continue the NMSP until January 2010 and will continue to review new and significant new use nanomaterial data submitted under TSCA.

Occupational health regulatory oversight of nanomaterials is as limited as environmental oversight. Federal regulation of workplace hazards is the responsibility of OSHA under the OSHAct. As a result of several court rulings, OSHA is required to conduct comprehensive risk assessments as part of the rulemaking process, seriously slowing OSHA's ability to update health standards for even well-established workplace hazards, such as silica and beryllium. Given OSHA's regulatory burden of proof, the lack of detailed risk assessment data for nanomaterials suggests that it will be many years before OSHA can establish regulations for these materials. Currently the best available guidance on nanomaterial workplace health and safety is provided in best practice documents from the Department of Energy (DOE), NIOSH, and international standards such as the ISO/TR 12885.

3.2 State Initiatives

In April 2009, California lawmakers began considering whether nanomaterials should be regulated under the State's Green Chemistry Initiative, a program housed in the Department of Toxic Substances Control. The proposal's opponents have suggested that nanomaterials should be regulated under their own program at the California Environmental Protection Agency (Cal/EPA). It is expected that any proposed legislation will include a mix of mandatory and voluntary measures. The timeline for promulgation remains to be determined, yet the initiative indicates that nanomaterials are on the proverbial radar screen.

Other States most able to initiate legislative activities include Massachusetts, Michigan, New Jersey, and New York.[67] This judgment is based on these States' existing toxics reduction programs and aggressive air, water, waste, and work safety regulations. It remains unknown whether these States will consider nanomaterial-specific regulations or incorporation of nanomaterials into existing regulatory frameworks in the State environmental health agency or occupational health agency. Future initiatives would depend on political, economic, and social drivers at both the State and Federal levels.

In the past, the DoD has sought exemptions from State and Federal laws, arguing that these exemptions are needed to preserve training flexibility and ensure military readiness. These exemptions have been the source of disagreement in Congress. The absence of data demonstrating how these statutes have restricted training and affected readiness and concerns about human health and environmental risks have motivated strong opposition to broad DoD exemptions. In February 2009, the Military Responsibility Act (H.R. 672) was referred to the House Subcommittee on Readiness. This Act would require the DoD to fully comply with designated State and Federal laws designed to promote environmental and occupational health and safety. Should State- or Federal-level nanomaterial regulation be enacted, the Army and other DoD Components should be prepared to adhere to the regulations and comply with the regulation as written.

3.3 Local Initiatives

In December 2006, the city of Berkeley, California adopted local regulation that requires all facilities that manufacture or use manufactured nanomaterials to submit a written disclosure to the City Council.[68] The disclosure must include toxicology information for the nanomaterials, as well as methods for safe storage,

[65] Untied States Environmental Protection Agency (2009)
[66] Willis (2009)
[67] Keiner (2008)
[68] Keiner (2008)

handling, and disposal. The City Council recommends internal audits to evaluate potential exposure risks during the life cycle of the product. In the absence of toxicity information, a precautionary approach is advised, i.e., assume the nanomaterial is dangerous to human health and the environment.

Cambridge, Massachusetts is the only other local jurisdiction that has approached the possibility of regulating nanomaterials. In July 2008, the Cambridge Public Health Department reviewed a report published by the Cambridge Nanomaterials Advisory Committee, a group formed to provide an independent risk assessment. The report provided information on the potential impacts of the nanotechnology sector on public health and the impact of regulations on research and development. In response, the Cambridge Public Health Department recommended that the City of Cambridge not enact a new ordinance regulating nanotechnology but, instead, conduct the following activities:

- Establish an inventory of facilities that manufacture, handle, process, or stored nanomaterials;
- Offer technical assistance, in collaboration with academic and nanotechnology industry partners, to help firms and institutions evaluate their ESOH plans;
- Offer up-to-date health nanotechnology product information to residents and sponsor outreach events;
- Track research and development initiatives concerning possible health risks from various engineered nanomaterials;
- Track the evolving status of regulations and best practices concerning nanomaterials at the State, Federal, and International levels and in industry groups; and
- Report back on the changing regulatory and safety landscape as it relates to the manufacture, use, and investigation of nanomaterials.[69]

No other local jurisdictions have legislative activities concerning nanomaterials.

3.4 International Oversight and Initiatives

Regulation No 1907/2006 is the central act of the European chemical policy known as REACH. REACH went into force in the European Union in June 2007. The REACH Regulation gives greater responsibility to industry to manage the risks from substances and provide safety information on the substances manufactured or imported in quantities greater than established thresholds. As compared with current USEPA regulations such as TSCA, the burden rests with manufacturers and importers of substances to gather information on the safe handling of their substances and register the information with the European Chemicals Agency. Chemical manufacturers must gain government authorization to use certain substances of very high concern.

Although there are no provisions in REACH referring specifically to nanomaterials, the regulation applies to substances regardless of size, shape, or physical state. Therefore, nanomaterials are covered by REACH and manufacturers and importers will have to ensure that the nanomaterial does not adversely affect human health or the environment.[70] Similar to TSCA, if a substance already exists on an inventory of chemicals, in the case of REACH the European Inventory of Existing Commercial Chemical Substances (EINECS), then it is considered an existing substance. Under REACH, existing substances are classified and treated as phase-in substances and, depending on the quantity manufactured or imported, can benefit from extended registration deadlines. An example of a nanomaterial substance that is classified as a phase-in substance is titanium dioxide. An example of nanomaterial substances that are not classified as phase-in substances are carbon allotropes (different structural forms of the element carbon).[71] Registration of a nanomaterial will have to include all relevant information on the nanomaterial as manufactured or imported, and cover the properties, uses, and exposure-related information as well as the relevant classification and labeling, safety assessment, and relevant exposure scenarios.

[69] Cambridge Public Health Department (2008)
[70] European Commission (2008)
[71] European Commission (2008)

REACH has possible implications for U.S. military operations and maintenance in the European Union, such as disruption of defense supply chains, and increased research and development costs.[72] The magnitude of these impacts is uncertain because of the many outstanding issues regarding the application of REACH to nanomaterials.[73] In response to these unknowns, the DoD convened a multidisciplinary, joint effort to develop a strategic plan for REACH. As of April 2009, a draft plan was in development and undergoing review.

Further work is planned on the application of REACH to nanomaterials.[74] For example, since its inception two years ago, recommendations have been made by the Environment Committee of the European Parliament to change REACH such that it better addresses substances at nanoscale. Specific changes may include requirements for chemical safety reports with exposure assessment information for all registered nanomaterials, as well as simplified registration processes for nanomaterials based on factors other than quantity manufactured or imported, and notification for all nanomaterials placed on the market.[75]

Several countries are moving forward with the enactment of national regulations that would require manufacturers to evaluate the ESOH risks of nanomaterials and aid in the development of appropriate safety measures to protect human health and the environment. As of January 2009, Environment Canada had promoted regulatory activity that would require reporting on the quantity, use, and toxicity of nanomaterials, yet the ruling was delayed. Despite this delay, it is apparent that the trend is towards increased regulatory safeguards for nanomaterial research, development, manufacturing, and commercialization.

4 Integrating Life Cycle Principles and Risk Frameworks

4.1 Risk Assessment and Management

Risk assessment is a process in which information is analyzed to determine if exposure to a hazard may result in adverse affects to human health or the environment. It is a tool to integrate exposure and effects information from multiple disciplines and characterize impacts to populations. Risk managers use risk assessment to guide their decisions and to develop policies that promote human health and the environment.

The elements of the risk assessment and management processes are research, assessment, and management.[76] The process is iterative and should include stakeholder input at each phase of the process. Research includes laboratory and field observations of exposures and measurements to estimate exposures and characterize affected populations. The assessment component comprises hazard identification, dose-response assessment, and exposure assessment methods and techniques which are used to characterize the nature and magnitude of the risk posed by the hazard. Figure 5 provides an illustrative interpretation of the risk assessment process. Management of risk involves development and execution of regulatory or policy options after an evaluation of economic, environmental, social, and political consequences and takes place after the risk assessment is completed.

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[72] Department of Defense (2009a)
[73] European Commission (2008)
[74] European Commission (2008)
[75] EurActiv Network (2009)
[76] National Research Council (1983)

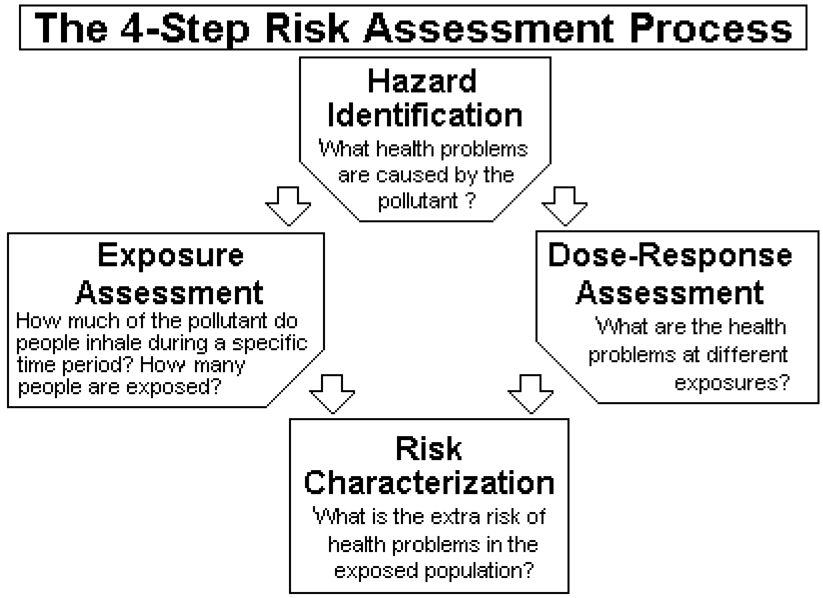

Figure 5. Four Step Risk Assessment Framework[77]

The scientific characterization of risk is based on a detailed, systematic, rigorous analysis of available information. For each risk assessment, the assessor selects an approach that is consistent with the scope of the decision to be made. The appropriate approach depends on the needs of the decision maker and the role the risk information plays in the decision, balancing uncertainty and resources. It is very specific to a process or activity, a site, a pathway, a population, or an endpoint. The analysis must consider areas where information is uncertain or absent, yet remain accurate, balanced, and informative. Given that uncertainty is inherent, there is a continuing tension between improving our understanding in order to make a decision, the reality of limited resources to perform the analysis, and the desire for timely decision making.

4.2 Army Risk Assessment and Management

4.2.1 DoD System Safety

In the DoD, the standard practice used to assess and manage mishap risks encountered in the development, test, production, use, and disposal of DoD systems, subsystems, equipment, and facilities is a system safety approach per Military Standard (MIL-STD) 882D. This includes environmental, safety, and health risks. The mishap risk assessment process identifies hazards through a systematic hazard analysis process, characterizes hazards within technical processes, analyzes hazards for their potential severity and probabilities of occurrence, and prioritizes hazards for risk mitigation actions. The minimum mandatory requirements for a system safety program for any DoD system are listed below.[78]

1. Document the system safety approach.
2. Identify hazards that could occur over the system life cycle.
3. Assess the severity and probability of the mishap risk for each identified hazard.
4. Identify mishap risk mitigation measures using the following order of precedence: eliminate hazards through design selection, incorporate safety devices, provide warning devices, and develop procedures and training.

[77] USEPA (1991)
[78] DoD (2000)

5. Reduce the mishap risk to an acceptable level through a mitigation approach mutually agreed to by the developer and program manager.
6. Verify mishap reduction through analysis, testing, or inspection and report any new hazards identified.
7. Obtain review and acceptance of remaining hazards and residual mishap risk by the appropriate risk acceptance authority.
8. Track hazards, their closures, and residual mishap risk throughout the system life cycle.

When properly applied, the system safety approach should ensure the identification, understanding, elimination or reduction of known hazards and their associated risks.

4.2.2 Army Safety Program and Composite Risk Management

The safety program requirements for the Army and subordinate commands are established in the Army Regulation (AR) 385 Series. Per AR 385-10, the assessment and management of risk takes the form of composite risk management (CRM).[79] Composite risk blends tactical, threat-based risks with accidental, hazard-based risks. CRM processes identify and manage risks to personnel, missions, operations, training, procedures, equipment, and the environment to avoid loss of life, injury or illness, property loss or damage, or environmental harm throughout the life cycle of systems, facilities, and equipment. CRM is integrated into all Army decision-making processes. Army leadership at all levels advance safety practices and CRM through the application of new technologies, innovative best practices, and improved risk assessment and management tools.

Department of Army Pamphlet (DA PAM) 385-10[80] provides guidance and establishes procedures for complying with the Army Safety Program requirements of AR 385-10. DA PAM 385-10 identities system safety and the following steps for reducing risk throughout the design, development, production, fielding and deployment of a system.

1. Plan the safety program, describing the system and identifying the people, safety processes, equipment and other factors that are required for a successful safety program.
2. Identify the hazards associated with the planned system, update regularly as the system design becomes more defined, and develop safety input for various system documents.
3. Develop a methodology for tracking each hazard and progress towards developing a corrective action.
4. Evaluate the potential impact (probability and severity) of identified hazards, determine the costs and benefits of eliminating the hazard, and identity new hazards.
5. Prioritize hazards and enter each hazard and mitigation effort into a hazard tracking system.
6. Control the decision process on hazard mitigation, which includes managing the safety and risk management process and regularly briefing the status of system safety and corrective actions to management, technical and other members of the acquisition team.

DA PAM 385–30[81] provides a framework for integrating the Mishap Risk Management Process of CRM into all phases of Army operations using the following steps.

1. Identify hazards that may be encountered in executing an activity.
2. Evaluate each hazard and assign a level of risk based on the estimated probability and severity for the likelihood and impact of the hazard.
3. Develop possible countermeasures, balance risk against impact to mission, cost, performance and schedule, and make decisions to eliminate unnecessary risks.
4. Implement controls.

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[79] Department of the Army (2007b)
[80] Department of the Army (2008a)
[81] Department of the Army (2007a)

5. Supervise and evaluate by continuously assessing the risk to overall mission and those involved in the task, evaluating the effectiveness of controls, and providing lessons learned so others may benefit from the experience.

In addition to CRM, DA PAM 40-503 (Industrial Hygiene Program) provides a risk management framework for anticipating, recognizing, evaluating, and controlling risks posed by hazardous materials. DA PAM 40-503 is in the process of being updated to include risk management references specific to nanomaterials.[82]

4.2.3 DoD Nanomaterials Working Group Memo

To ensure a consistent message regarding the DoD's assessment and management of ESOH nanomaterial risks, the Office of the Secretary of Defense Chemical and Material Risk Management (CMRM) Directorate and the DoD Nanomaterials Working Group (WG) produced a memo in May 2008 reinforcing responsibilities in DoD research, acquisition, operations, and support activities. The memo states that:

- DoD ESOH professionals should exercise due diligence in meeting their responsibilities to protect the health and safety of workers, the public, and the environment and shall maintain current knowledge of ESOH risks and provide Science & Technology managers, program managers (PMs), and users with risk management options required by Department of Defense Instruction (DoDI) 6055.5 (Occupational and Environmental Health).[83]
- DoD nanotechnology developers and users shall follow DoDI 6050.05 (Hazard Communication Program)[84] for storage and use of nanomaterials in the workplace.
- DoD Science & Technology managers should support ESOH risk research to close information gaps.
- DoD Program Managers must ensure ESOH hazards are identified and the associated risks managed pursuant to DoDI 5000.2 (Operation of the Defense Acquisition Systems)[85], Military Standard 882D (Standard Practice for System Safety)[86], and other DoD policy requirements.

It is the responsibility of Service- and Agency-specific ESOH personnel to ensure the memo has been distributed and its objectives have been met.

4.3 Life Cycle Assessment

Life cycle assessment (LCA) is a systematic, analytical process for quantifying the inputs and outputs for each life cycle stage and assessing the total environmental impact of a product. The four phases of LCA, listed below, are described in the ISO 14040 LCA and accompanying standards.[87]

1. ***Goal and scope definition*** – specify the reason for conducting the study, intended use of study results, and intended audience; and identify system boundaries, data requirements, and study limitations.
2. ***Life cycle inventory (LCI) analysis*** – collect, validate, and aggregate input and output data to quantify material use, energy use, environmental discharges, and waste associated with each life cycle stage.
3. ***Life cycle impact assessment (LCIA)*** – evaluate the significance and potential effects of the LCI on a set of natural resource and environmental categories (e.g., fossil fuel or water

[82] Chris Carroll, USACHPPM, personal communication, April 28, 2009
[83] Department of Defense (2008b)
[84] Department of Defense (2008c)
[85] Department of Defense (2008a)
[86] Department of Defense (2000)
[87] International Organization for Standardization (2006)

consumption, land use, ozone depletion, global warming, acidification, eutrophication, tropospheric ozone formation, ecotoxicity, and human toxicity).

4. ***Interpretation*** – iteratively with other LCA phases, assess whether results are in line with defined goals and scope, provide an unbiased summary of the results, define significant impacts, and recommend methods for reducing material use, energy use, and environmental burdens.

The simplified process schematic in Figure 6 represents the life cycle stages associated with nanomaterials used by DoD. Raw materials are extracted (stage 1) and used to produce useful materials, including nanomaterials (stage 2). These materials are incorporated into products (stage 3), which are used (stage 4) and eventually retired (stage 5). Throughout the life cycle, the use and transportation of materials and energy generates useful products, but also results in environmental discharges and generates waste. In the case of nanotechnology, environmental discharges and waste could include nanomaterials. Evaluating the total environmental impacts of a product requires analysis of the inputs and outputs associated with each life cycle stage.

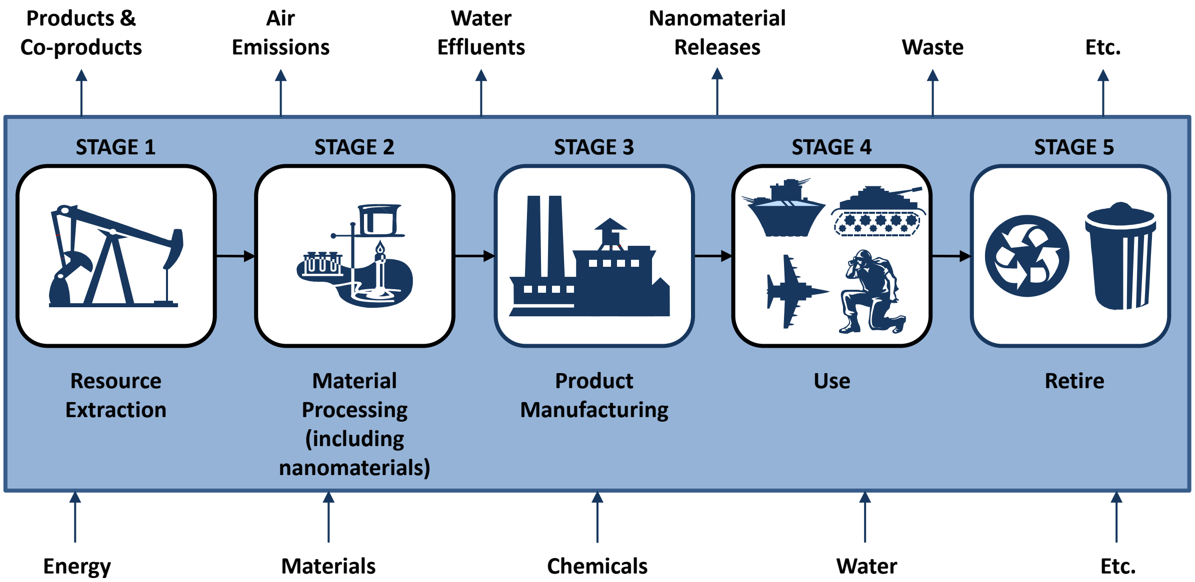

Figure 6. Life Cycle Stages Associated with Using Nanomaterials for Defense Applications

To date, most of the available nanomaterial LCAs have focused on specific stages of the life cycle. Some of the more interesting findings are listed below.

- Strict material purity requirements, low yields, toxic chemical use, and high energy requirements of nanomanufacturing may have a significant environmental impact.[88]
- The life-cycle environmental impacts of carbon nanofiber production may be as much as 100 times greater per unit of weight than those of traditional materials.[89]
- Improvements to automotive catalysts from nanofabrication could significantly reduce platinum group metal mining and refining and, as a result, the environmental impacts from the resource extraction and material processing stages.[90]
- Use of nanocomposites to reduce the weight of automotive body panels could improve vehicle fuel economy thereby reducing fuel consumption and the associated emissions.[91]

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[88] Şengül et al. (2008)
[89] Khanna et al. (2008)
[90] Lloyd et al. (2005)
[91] Lloyd and Lave (2003); Roes et al. (2007)

Many of the LCAs have focused on a single life cycle stage (e.g., nanomaterial production). Few have evaluated the full life cycle of commercial products. The types of impacts evaluated ranged from single impacts (e.g., greenhouse gas emissions and the related global warming potential) to a more complete set of life cycle impact assessment categories. None of the LCAs conducted to date have evaluated the impacts associated with nanomaterial releases, because there simply is not enough information to accurately quantify nanomaterial releases, fate, or environmental impacts. While LCA has provided important insights on certain life cycle impacts from producing and using nanomaterials, it has not informed the discussion about the specific risks from nanomaterial releases or waste products.

4.4 Life Cycle Risk Assessment

Current efforts are underway to integrate risk assessment and LCA concepts to identify and evaluate nanomaterial risks. However, the approaches proposed so far do not include the specific steps of an LCA, nor do they evaluate the impact categories included in LCA. Rather, they focus primarily on the specific risks from exposure to hazardous materials over the life cycle of a system. Three life cycle risks assessment approaches are described here. While the focus of each is on nanomaterials and products containing nanomaterials, the concepts can be used to evaluate the life cycle risks associated with any material or technology.

4.4.1 Nano Risk Framework

In 2005, Environmental Defense (ED) and DuPont entered into a partnership, which resulted in gathering a multidisciplinary team from both organizations, and developing an approach to address the potential EHS risks of nanotechnology. The Nano Risk Framework, shown in Figure 7 was released in 2007. The specific steps of the Nano Risk Framework are listed below.

1. Describe nanomaterial and intended uses.
2. Profile the nanomaterial's properties, inherent hazards and associated exposures throughout the material's life cycle.
3. Identify and characterize the nature, magnitude, and probability of risks presented by this particular nanomaterial and its anticipated application.
4. Evaluate the available options for managing the identified risks and recommend a course of action.
5. Decide whether to continue development and production, document decisions and communicate to stakeholders, initiate action to gather additional necessary as needed, and define triggers for future updates and reviews of the risk evaluation and risk management decisions.
6. Perform reviews to update the risk evaluation, evaluate whether the risk management systems are working as expected, and adapt.[92]

[92] Environmental Defense – DuPont Nano Risk Framework (2007)

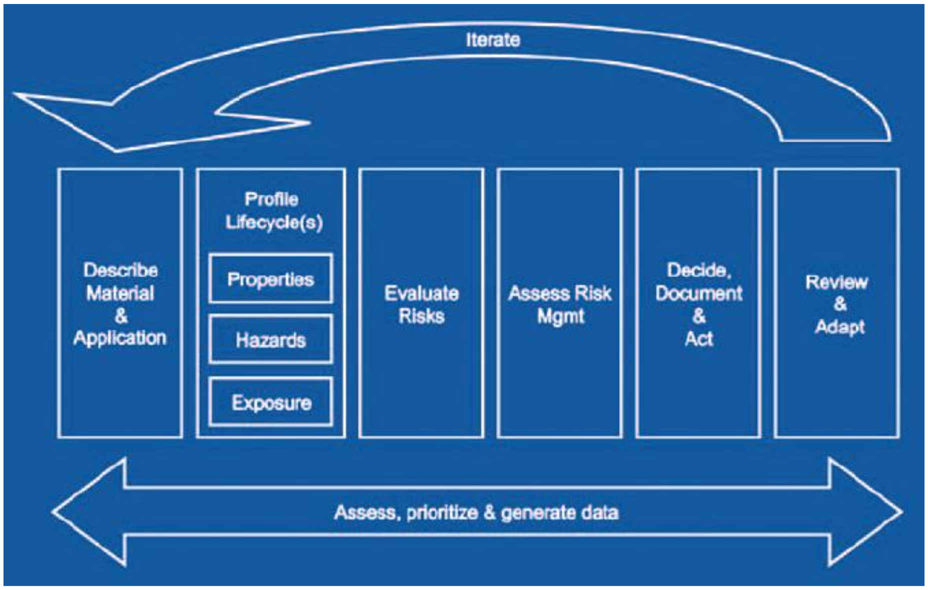

Figure 7. Environmental Defense - DuPont Nano Risk Framework[93]

The Nano Risk Framework focuses on evaluating and reducing the potential environmental, health, and safety risks from nanomaterials across a product's life cycle. The primary intended user group includes organizations working with nanomaterials and developing products that employ nanomaterials for industrial, chemical, manufacturing, and consumer applications. It recommends the use of "reasonable worst-case assumptions" or comparisons to other better characterized materials where hazard or exposure information is lacking. More information and case studies on surface-treated high-rutile phase titanium dioxide, single-walled and multi-walled carbon nanotubes, and nano-sized zero-valent iron are available on the Nano Risk Framework website.[94]

4.4.2 Comprehensive Environmental Assessment

In developing the Alternative Fuels Research Strategy for comparing the benefits and risks of motor vehicle fuels, USEPA combined product life cycle and risk assessment frameworks to identify the key issues resulting from methyl tertiary butyl ether (MTBE) usage.[95] The approach is now known as comprehensive environmental assessment (CEA).[96] It has been proposed for identifying the knowns and unknowns needed to conduct risk assessments, prioritizing research efforts, and managing unforeseen impacts as they emerge.[97]

As in the Environmental Defense – DuPont Nano Risk Framework, the focus is on the toxic potency of contaminants (rather than the full set of LCA impact categories). However, the focus is on nanomaterials as well as associated materials (e.g., manufacturing by-products) and transformation products. In addition, it is acknowledged that the other risks and benefits of the product life cycle (e.g., the full set of LCA impact categories) as well as public opinion should be considered in evaluating a given application. The activities included in CEA are listed below.

1. Identify the life cycle stages of a product, including feedstock production or extraction, manufacturing, distribution, storage, use, and disposal of the product and waste byproducts.

[93] Environmental Defense – DuPont Nano Risk Framework (2007)
[94] http://www.nanoriskframework.com/
[95] Davis (2007); Environmental Protection Agency (1992)
[96] Davis and Thomas (2006)
[97] Davis (2007)

2. Identify the primary materials (e.g., nanoscale substances) and associated materials (e.g., manufacturing by-products) that might enter environmental pathways (i.e., air, water, solid and food web) throughout the entire life cycle.
3. To the extent possible, characterize the transport and transformation processes that the primary pollutants and transformation products (i.e., secondary pollutants) undergo for all relevant media.
4. For all exposure routes (e.g., inhalation, ingestion, and dermal absorption), characterize the potential aggregate exposure across routes and cumulative exposure to multiple (i.e., primary and secondary) pollutants. Consider the range of exposure scenarios, including microenvironmental and high-end exposures.
5. Quantitatively and/or qualitatively characterize the health and ecological hazards and risks associated with the various contaminants.

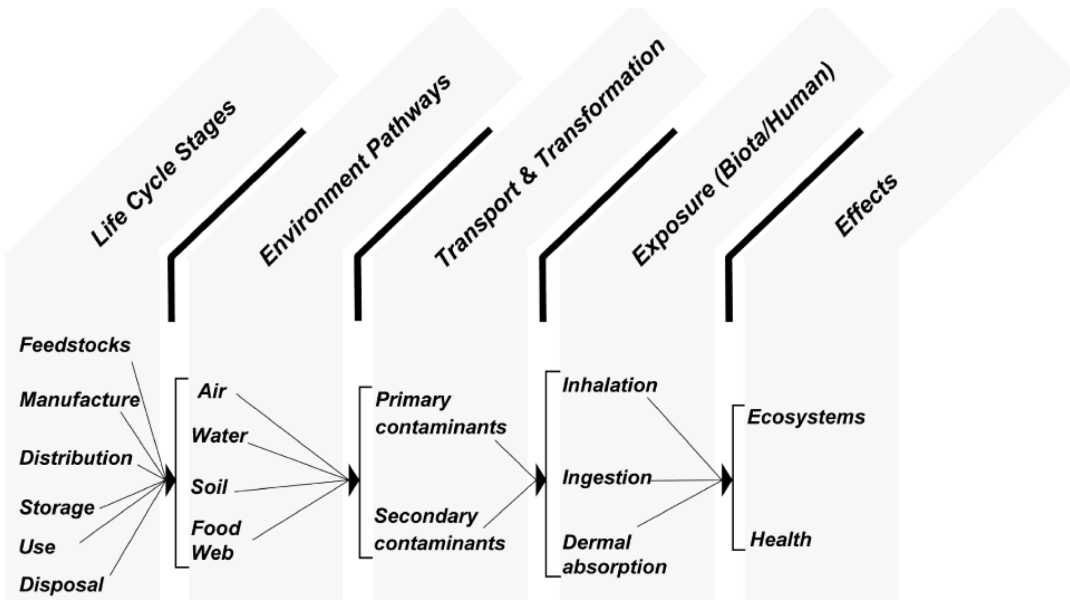

Figure 8. CEA Approach to Identifying and Prioritizing Research Efforts for a Nanoscale Product[98]

A 2007 USEPA white paper on the implications and applications of nanotechnology recommended that the Agency conduct case studies based on publicly available information to identify unique risk assessment considerations for nanomaterials and examine how nanomaterial assessment would fit in USEPA's overall risk assessment paradigm.[99] USEPA staff are currently applying the CEA approach to evaluate three nanomaterial applications: nanoscale titanium dioxide for water treatment; nanoscale titanium dioxide for sunscreen applications; and nanoscale silver (specific application not yet determined).

4.4.3 NANO LCRA

In *Nanotechnology Health and Environmental Risks*, a recognized expert in assessing the environmental and human health risks of nanotechnology proposed a screening framework based on life cycle thinking and risk assessment.[100] The Nano life cycle risk assessment (LCRA) framework is a screening tool for identifying and prioritizing key health and environmental issues early in nanomaterial development when little risk assessment information is available. The Nano LCRA framework is shown in Figure 9 and its steps are listed below.

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[98] Davis (2007); Davis and Thomas (2006)
[99] United States Environmental Protection Agency (2007)
[100] Shatkin (2008)

1. Describe the life cycle of the product.
2. Identify the materials and assess potential hazards in each life cycle stage.
3. Conduct a qualitative exposure assessment for materials at each life cycle stage.
4. Identify stages of life cycle when exposure may occur.
5. Evaluate potential human and non-human toxicity at key life cycle stages.
6. Analyze risk potential for selected life cycle stages.
7. Identify key uncertainties and data gaps.
8. Develop mitigation/risk management strategies and next steps.
9. Gather additional information.
10. Iterate process, revisit assumptions, adjust evaluation and management steps.

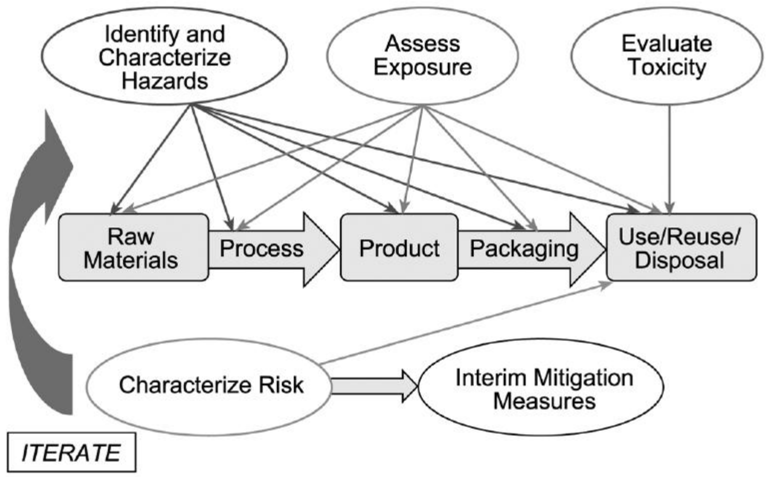

Figure 9. NANO LCRA Adaptive Screening Risk Assessment Framework[101]

The Nano LCRA framework uses available information and professional judgment to approximate the significance of potential impacts, identify which life cycle stages may be of concern, inform control strategies, and prioritize future work for addressing key uncertainties to better characterize risk. To bridge the divide between precautionary and analytical approaches, it suggests that high uncertainty be addressed by adopting risk-averse strategies. The primary intended user group includes nanomaterial producers as well as producers and users of products containing nanomaterials. The Nano LCRA framework focuses on adverse effects from human and non-human exposure to nanomaterials and nanomaterial related mishaps (e.g., explosion hazards), but also considers risks associated with other materials within the product life cycle. A case study is presented for nanoscale iron particles used to break down tetrachloroethylene (PCE) and trichloroethylene (TCE) in groundwater.

4.5 Evaluation of Frameworks

Each of the frameworks discussed above were evaluated based on four objectives: effective risk assessment, management, and communication; consideration of full life cycle; ability to support sustainability, and applicability to nanomaterials. The following elements were identified as necessary for or effective risk assessment, management, and communication.[102]

- Multidisciplinary
- Clearly defined roles and responsibilities
- Clear problem formulation
- Clearly defined approach

[101] Shatkin (2008)
[102] For example, see Jardine et al. (2003) and van Leeuwen, C.J and Vermeire (2007)

- Stakeholder involvement
- Communication
- Hazard identification
- Exposure assessment
- Response assessment
- Risk characterization
- Informed decision making
- Evaluation (to determine effectiveness)
- Iteration (to accommodate new information)
- Transparent
- Flexible
- Documentation

To ensure that the full life cycle is considered, the life cycle context must be defined during the problem formulation state and addressed throughout the risk assessment, management, and communication processes.

To effectively support sustainability, disparate impacts associated with a course of action must be considered together, including, for example, performance, costs, risks, and benefits. Risk cannot be evaluated in isolation. Rather, decision makers need to consider other impacts on the mission, environment, and community. For example, the results of the risk assessment can be considered in conjunction with the results of other assessments, including performance testing, LCA, and life cycle cost analysis (LCCA). In addition, to effectively maximize desired outcomes and minimize undesired outcomes, the system of interest should be compared to other courses of action.

Table 6 presents a comparison of LCA, risk assessment, and risk management frameworks. The iteration element was expanded to include three steps: identify key uncertainties and data gaps, gather additional data, and iterate to accommodate new information (e.g., collected as part of this process or developed by the scientific and professional communities at large). The informed decision-making element was expanded to include three steps: develop risk management strategies, select a strategy, and implement the strategy. The transparency and flexibility elements were not included since they are characteristics rather than steps of the risk assessment, management and communication processes.

The documents identified in the previous sections were reviewed to determine extent to which each of these steps is included as part of the framework. While LCA is not a risk assessment and management framework, it was included to demonstrate features included in LCA, but not yet included in some life cycle risk assessment and management frameworks.

Table 6. Comparison of Risk Assessment, Management and Communication Frameworks

Step	MIL-STD - 882D	AR 385 & CRM	LCA	NANO Risk	CEA	NANO LCRA
Assemble multidisciplinary team	✓	✓		✓	✓	
Define roles and responsibilities	✓	✓	-	✓	-	
Formulate problem	-	✓	✓	-	-	-
Establish life cycle context	✓	✓	✓	✓	✓	✓
Identify and engage stakeholders	-	-	-	✓	✓	-
Define approach and tools	✓	✓	✓	-	-	-
Characterize materials				✓	✓	-
Identify hazards	✓	✓		✓	✓	✓
Assess exposure	✓	✓		✓	✓	✓
Assess severity and probability of response	✓	✓		✓	✓	✓
Characterize risk	✓	✓		✓	✓	✓
Identify key uncertainties and data gaps			-	✓	✓	✓
Gather additional information	-	-	✓	✓	✓	✓
Evaluate other life cycle impacts	-	-	✓			
Compare to other options		-	-		-	✓
Develop risk management strategies	✓	✓		✓	-	✓
Select a strategy	✓	✓		✓		✓
Implement the strategy	✓	✓		✓		✓
Monitor, review and evaluate	✓	✓		✓	-	✓
Document findings, decisions, results	✓	✓	✓	✓		✓
Communicate throughout the process	✓	✓		✓		
Iterate to accommodate new information	-	-		✓	✓	✓

Legend
✓ = Explicitly included as part of the framework
\- = Topic included but not a specific element of the framework
(shaded) = Minimal/no consideration within the framework

The comparative analysis presented in Table 6 yields the following observations:

- All frameworks focus on managing risks (or impacts in the case of LCA) across a system's life cycle.
- The DoD system safety (MIL-STD 882D) and the Army CRM frameworks are much broader than the other frameworks considered. They integrate ESOH management into the system engineering process.
- Risk assessment and LCA tend to focus on materials with known hazards. By contrast, the extent to which new materials, such as nanomaterials, may harm biological systems is often not known. To capture this identified unknown in the analysis, novel materials, such as nanomaterials, should be characterized and considered throughout the analysis. Supplemental guidance may be needed for considering the risks of specific materials, such as nanomaterials.
- The Nano Risk, CEA, and Nano LCRA frameworks start with the assumption that nanomaterials should be evaluated. Since most nanomaterials have not been identified as hazardous, the DoD system safety and the Army CRM frameworks may not identify them as a material of concern. Specific requirements may be needed to spur the consideration of novel materials, such as nanomaterials, for which little or no hazard information is available.
- In the frameworks considered, there is very little guidance on evaluating risks in concert with other life cycle impacts or comparing the performance of different options. Instead, the focus tends to be on identifying and reducing or eliminating unacceptable risks. Sustainability is better supported by evaluating tradeoffs between options and selecting options that minimize undesirable outcomes and maximize desired outcomes.

- In the DoD system safety and the Army CRM frameworks, available information is collected and used to support decision making. The assessment and decisions are updated throughout the life cycle, when the conditions change, or when new risks are identified. The iteration aspects of the Nano Risk, CEA, and Nano LCRA frameworks are more adaptive. Key uncertainties and data gaps are identified. Prior to proceeding, efforts may be initiated to reduce the uncertainty or fill these data gaps. As new information becomes available (e.g., for the technical or scientific community at large), the assessment and decisions are updated.
- The DoD system safety and the Army CRM frameworks provide more detail related to assembling a multidisciplinary team, defining roles and responsibilities, defining the specific approach and tools to be used, documenting and communicating throughout the process.
- Stakeholder engagement is explicitly part of the Nano Risk and CEA frameworks.

5 Risk Assessment and Risk Management Tools

The risk assessment and management frameworks presented in Section 4 are implemented using a variety of tools currently available to Army risk assessors and managers. Whether risk assessment is completed using a system safety approach or a CRM approach, the tools to collect, analyze, and communicate information on hazards may limit their application to situations where there are known hazards. Development of techniques for monitoring for nanomaterials in the workplace and the environment are hindered by the fact that biological and environmental pathways for nanomaterial remain unknown.

Although various levels of human and environmental toxicity have been reported for different nanomaterials, e.g., fullerenes, carbon nanotubes, quantum dots, and nanoparticles containing metal oxides, the studies were not conducted with a focus on risk assessment. That is, the studies used non-standardized tests, had no coherent endpoint, and differed substantially with regard to duration of exposure and effects observed and reported.[103] Thus, risk experts are concerned that the current risk assessment and management tools may be inadequate to assess the unique features of nanomaterials.[104]

An innovative approach to assessing hazards from this emerging contaminant is needed, and a life cycle risk approach presents the best option. However, life cycle risk tools are not as mature as risk assessment tools and are not readily available to Army personnel. Until life cycle risk tools are developed or existing risk frameworks supplemented with life cycle risk approaches, the established risk assessment tools should be used to address potential ESOH risks. This section reviews some of these tools and provides examples of how they can be applied to identify and manage ESOH risks from nanomaterials.

5.1 Precautionary Principle

The precautionary principle is the basis for environmental and occupational health policy. In practice, the precautionary principle is the obligation to prevent or minimize potential harm. Decision makers apply this principle when the risk cannot be fully quantified or demonstrated due to insufficient scientific data.

The application of a nanomaterial-specific precautionary principle requires that there is a preliminary scientific evaluation showing reasonable grounds for concern that the material may lead to adverse human health or environmental impacts. The comprehensive 2009 EMERGNANO paper concluded that for the majority of nanomaterials (but not all nanomaterials) the body of evidence identified was not sufficient to conclude that the precautionary principle was applicable.[105] Regardless, the authors of the

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[103] Hansen (2009)
[104] Hansen (2009) and NSET sponsored National Nanotechnology Initiative Human and Environmental Exposure Assessment Workshop in Bethesda, MD. February 24-25, 2009
[105] Aitken et al. (2009)

paper suggest caution in using nanomaterials and the application of the precautionary principle to certain nanomaterials, e.g., nanotubes.

5.2 Hazard Communication

The principle undergirding hazard communication is that employees have the right to know about the hazards of the chemicals they may encounter on the job. OSHA's Hazard Communication Standard (29 Code of Federal Regulations (CFR) 1910.1200) requires that employers provide workers with information on the physical and health hazards of the chemicals used onsite and how to safely use these chemicals to reduce the potential for occupational injury or illness. A written Hazard Communication Program must include information on training workers, labels, Material Safety Data Sheets (MSDSs), a chemical inventory, and response and preparedness actions for accidental releases of chemicals.

Hazard communication in laboratory settings requires application of OSHA's "Occupational Exposure to Hazardous Chemicals in Laboratories" standard (29 CFR 1910.1450). This standard requires that facilities using hazardous chemicals at the laboratory scale develop a written Chemical Hygiene Plan that ensures lab employees are protected from health hazards through implementation of standard operating procedures relevant to safety and health, via effective engineering controls, and by sharing information through training.

The DoD's Hazard Communication Program (DoD Instruction 6050.05) is one example of a risk management plan employed by the DoD and the Services to ensure potential chemical hazards are assessed and communicated to stakeholders, e.g., workers. It is a broad-brush program that provides specific sites with flexibility in meeting these requirements. Per the DoD Nanomaterial Working Group memo published in May 2008, the DoD's Hazard Communication Program applies to nanomaterials.

5.3 Hazard and Operability Method

The hazard and operability (HAZOP) method brings together those personnel involved with an operation to brainstorm ideas about potential hazards associated with process flow. The method provides a systematic, stepwise team approach to assessing and analyzing hazards and mitigating risks. HAZOP is used to identify potential hazards and operability problems caused by deviations from the design intent of both new and existing processes.

The Safety and Risk Management personnel at the ARL are responsible for assessing and managing ESOH risks posed during laboratory research. ARL uses mini HAZOP studies, in addition to the Army’s CRM approach,[106] to assess and manage hazards and ensure scientists, engineers, maintenance personnel, and ESOH personnel contribute to the safe operation of specific processes. ARL personnel currently use the mini HAZOP method to assess and manage ESOH risks unique to nanomaterials used in their facilities.

The HAZOP process complements the Army's CRM process and is well suited to RDT&E environments. It involves a systematic, iterative assessment to identify potential problems throughout a process. A general HAZOP consists of the following stages:

- Stage 0: Pre start-up (access control, review of standard operating procedures)
- Stage 1: Shipping/receipt of material (inventory methods, Material Safety Data Sheet [MSDS], spill response)
- Stage 2: Pre-use storage (refrigeration, special requirements)
- Stage 3: Transfer to hood/use (containers, spill response)
- Stage 4: Use/experimentation (fire hazard potential, aerosol potential)
- Stage 5: End of use transfer (containers, spill response)

[106] Department of the Army (2006)

- Stage 6: Disposal (storage and shipment methods, decontamination)

5.4 Control Banding

Another risk management approach is control banding. This technique, often practiced in industry, determines control measures based on a classification or range of hazards and exposures. Control banding implements solutions that experts have previously applied to control occupational exposures effectively. The process, as it applies to nanomaterials, includes the following steps:

- Identification of potential adverse effects to human health and the environment from nanomaterials;
- Evaluation of tasks involving nanomaterials to identify potential exposure sources;
- Establishment of designated areas for control banding; and
- Management of written health and safety plans to reflect control banding practices and areas.

Lockheed Martin uses control banding in its management of environmental health and safety risks associated with nanomaterials.[107] The control banding implemented by Lockheed Martin considers ranges of exposure duration (e.g., from less than four hours per day for two days per week to more than eight hours per day for five days per week), potential for release (e.g., unbound materials, particles in friable matrices, or bound materials), and hazard (e.g., unknown properties, known to be inert). The factors and ranges are plotted on a matrix and control bands are applied. At Lockheed Martin, four bands are used for work with nanomaterials:

- Band 1: General ventilation and personal protective equipment (PPE)
- Band 2: Engineering controls and/or respiratory protection; additional PPE
- Band 3: Containment, e.g., glovebox
- Band 4: Specialist advise[108]

The control banding technique is teamed with corporate polices on nanomaterial management, collaborative communication of results, and regular participation in information exchanges to ensure commitment to safe development of nanotechnology.

5.5 Guidelines for Safe Handling and Use of Nanomaterials

Given the range of physicochemical properties of nanomaterials, the variety of occupational and environmental settings where nanomaterials may be found, the limited knowledge, and the limited regulatory oversight governing safe handling of nanomaterials, agencies and organizations have taken the lead in developing consensus guidelines. Table 7 highlights these guidelines and provides a summary of their key considerations.

[107] Lockheed Martin (2008)
[108] Lockheed Martin (2008)

Table 7. Example Guidelines for Safe Handling and Use of Nanomaterials

Author	Year	Title	Considerations
American Society for Testing and Materials (ASTM) International, ASTM E2535-07	2007	Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings[109]	Describes actions to minimize human exposure and covers handling principles and techniques in research and development activities, material manufacturing, and material use and processing.
British Standards Institute (BSI)	2007	PD 6699-2:2007 Guide to Safe Handling and Disposal of Manufactured Nanomaterials[110]	Prescribes four hazard categories with assigned benchmark exposure levels.
ISO	2008	ISO/TR 12885:2008 Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies[111]	Addresses health effects, exposure assessments, control practices. Designed to help companies, researchers, and workers to prevent adverse health and safety consequences during production, handling, use, and disposal of nanomaterials.
NIOSH	2009	Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials.[112]	Employers should take prudent measures to control occupational exposures in the manufacture and use of nanomaterials. Provides detailed discussion of factors that may affect occupational exposure to nanomaterials and includes a table of measurements methods and instruments used to evaluate exposure.
		Current Intelligence Bulletin 60: Interim Guidance for the Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles[113]	Recommends precautionary measures to control occupational exposures, hazard surveillance of nanoparticles as the basis for implementing controls, and continued use of established medical surveillance approaches to flag increases in frequency of adverse health effects potentially associated with occupational exposures to nanoparticles.
U.S. DOE	2009	The Safe Handling of Unbound Engineered Nanoparticles[114]	Establish safety and health (S&H) policies and procedures for nanotechnology-related activities involving Engineered Nanoparticles (ENP) as part of S&H program. Review nanotech plans for compliance with and inclusion in facility security and emergency management programs.

5.6 Publicly-Available Data

In addition to the published consensus guidelines, there are several databases developed, or currently being developed, that address safe handling and use of nanomaterials. Table 8 lists several databases.

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[109] Available for purchase at http://www.astm.org/Standards/E2535.htm
[110] Available at http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/
[111] Available for purchase at http://www.iso.org/iso/catalogue_detail?csnumber=52093
[112] Available at http://www.cdc.gov/niosh/topics/nanotech/
[113] Available at http://www.cdc.gov/niosh/topics/nanotech/
[114] Available at http://www.directives.doe.gov/pdfs/doe/doetext/neword/456/n4561.pdf

Table 8. Example Nanomaterial ESH Databases

Author	Year	Title	Considerations
Organisation for Economic Co-operation and Development (OECD)	2009	Database on Research into the Safety of Manufactured Nanomaterials[115]	This database is a clearinghouse of research projects addressing environmental, human health and safety issues of nanomaterials.
Rice University's International Council on Nanotechnology (ICON)	Beta Version	GoodNanoGuide[116]	The "Guide" will be based on Wiki format and will promote quick and easy communication among and between nanomaterial stakeholders concerning good practices.
Air Force	Beta Version	WINGS	WINGS will be a website that will provide access to tools for managing emerging nanomaterial ESOH risks, risk communication strategies, decision analysis tools, and best practices.

5.7 Consultation

At each site where nanomaterials are used, it is the responsibility of each worker to maintain a safe work environment and it is the responsibility of ESOH personnel on site to ensure compliance with necessary written health and safety programs. The U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) provides additional safety and health support for Army personnel. They have been actively engaged with identification of ESOH risks of nanomaterials and in the larger conversation being held at the international level, e.g., through participation in ISO/TC 229. USACHPPM personnel ensure Army documents reflect health and safety risks associated with nanomaterials, provide guidance to industrial hygiene personnel regarding nanomaterial exposure assessment, and communicate consensus guidelines regarding the safe use and handling of nanomaterials. For example, nanomaterial safety and health practices have been communicated to Army personnel via the Army's monthly industrial hygiene newsletter.

In addition to USACHPPM resources, several Army RDT&E facilities including the ERDC facility in Vicksburg, MS, have accessed guidance on safe handling and use of nanomaterials from the NIOSH Nanotechnology Field Research Team. NIOSH, through the Nanotechnology Research Center, has ongoing partnerships to conduct nanotechnology research with at least 24 different groups, including industry, academia, and government agencies in the U.S. and internationally. Their Nanotechnology Field Research Team uses information gathered from health hazard evaluations conducted in the field to develop workplace guidance documents designed for workplace environments.

5.8 Collaboration

The GoodNanoGuide Wiki and the WINGS initiatives demonstrate the trend towards collaboration and communication regarding ESOH risks. Collaborative efforts created by and for nanomaterial ESOH practitioners can provide a forum for dialogue with peers. Online collaboration minimizes impacts on travel budgets and maximizes added value because it allows communication with a global community who focus on this niche.

In addition to online collaboration, consortiums based on geographic location also minimize impacts on travel budgets and maximize added value. For example, the Southwest Nano Consortium was recently created to pool resources that will highlight nanotechnology activities in Arizona, Colorado, Oklahoma,

[115] Available at http://www.webnet.oecd.org/NanoMaterials/Pagelet/Front/Default.aspx
[116] Available at http://icon.rice.edu/centersandinst/icon/projects.cfm?doc_id=12207 for schedule updates

New Mexico, Texas, and northern Mexico. One objective of the consortium is to accelerate the "abilities to support and assist each other" to advance efforts related to nanotechnology.[117]

A third collaboration format is linkage of like-minded agencies. For example, the Environmental Council of the States (ECOS), a nonprofit association of State and Territorial environmental managers, supports a plan to integrate ongoing efforts to manage nanotechnology hazards. As of April 2009, they have tentatively scheduled discussions with states, the USEPA, and the DoD to address impact assessment and pollution prevention techniques with the objective of establishing best management practices. The effort by ECOS is one of the few focused on environmental health risk assessment and risk management methods.

Working groups are another form of collaboration. The International Life Sciences Institute (ILSI) Nanomaterial Toxicity Screening Working Group is a global network of scientists with the objective of developing a screening strategy for the hazard identification of ENP. Another example is the DoD Nanomaterials WG. This assembly of multi-Service and Agency personnel is tasked to address emerging and potential ESOH aspects of nanotechnology as they pertain to the DoD. Bimonthly meetings provide a forum for technical exchange and discussion of DoD-specific challenges for assessing ESOH implications and for managing potential ESOH liabilities.

6 Conclusions

The major source of concern regarding potential nanomaterial ESOH risks is from nano-sized particles that are not attached to a surface or are not part of a bigger item. These "free" nanoparticles can be transmitted via air, water (or other liquid or viscous medium), soil, vegetation, or biota resulting in unintentional human exposures via inhalation, ingestion, dermal or ocular routes. There is a lack of knowledge concerning the nature and magnitude of these risks and there is scientific uncertainty about the potential adverse effects of nanomaterials on humans or the environment. At this time, specific concerns include occupational exposures (e.g., carbon nanotubes, titanium dioxide, zinc oxide, and tungsten carbide cobalt) and environmental exposures (e.g., nanosilver, carbon nanotubes, and quantum dots). Quantities and concentrations at which these nanomaterials may be toxic are unknown.

While Federal regulatory frameworks are expected to be sufficiently flexible to cover nanotechnology, the variety of nanomaterials, lack of knowledge about their risks, and the diverse applications make it difficult to determine how and what to regulate. Potential actions to fill gaps in Federal oversight include policy initiatives at the international, State and local levels and through collaborative efforts of industry, academia, and government. Should Federal or State-level nanomaterial regulations come into existence, the Army should be prepared to comply. Failure to prepare for international regulations, such as the European Union's REACH policy, could have adverse impacts on the Army.

Despite uncertainty in exposure assessment methods and in regulatory approaches, Army ESOH and RDT&E personnel must apply the best available risk assessment and management methods and tools to identify and manage potential risks from nanomaterials. The Army manages risks in accordance with MIL-STD 882D, the AR 385 Series, and CRM. These risk management frameworks are implemented using a variety of tools, including hazard communication and the HAZOP method, as well as through consultation and collaboration with others. When properly applied, these risk assessment frameworks and tools should effectively identify and reduce or eliminate unacceptable known risks across a system's life cycle. However, improvements are needed to better support sustainability and more effectively consider the risks of novel materials, such as nanomaterials, for which little or no hazard information is available.

[117] Eurekalert (2009)

7 Recommendations

Good nanomaterial product stewardship requires a commitment to identifying and managing potential risks throughout a system's life cycle. A comprehensive nanomaterial risk management program is needed that identifies and prioritizes nanomaterials of concern, allows for quick adoption of the most recent ESOH risk assessment data, adheres to mandatory standards yet, in their absence, adopts voluntary best practices, and allows for participation in meaningful collaborative relationships.

Three specific recommendations for improving the Army's ability to identify and manage the life cycle ESOH risks of nanomaterials, given current scientific uncertainties, are listed below. Each represents an important aspect of life cycle risk management and would support a comprehensive nanomaterial risk management program. Since there are numerous nanomaterial types and variations that are likely to have both military, commercial, and industrial applications, the recommendations are relevant to the Army and to the other Services.

1. ***Adhere to published guidelines and best practices that are based on current risk assessment and management research.*** The NIOSH guidelines most recently updated in March 2009 address safe use and handling of nanomaterials in the workplace environment. The report, *Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials*, summarizes the safety and health risks to workers per recent exposure assessments conducted by the NIOSH Nanotechnology Field Research Team at various facilities actively engaged with nanomaterials RDT&E. The NIOSH report recommends prudent measures to minimize worker exposures including safe work practices, effective engineering controls, effective PPE, and waste management practices. NIOSH also recommends implementing an occupational health surveillance program as part of the existing occupational health and safety program to ensure continued evaluation of those workers who have potential for exposure to nanomaterials.

   At this time, there are no published reports that address safe use and handling practices unique to environmental releases. In absence of guidelines, application of existing best practices for the workplace may serve as prudent measures to manage risks to the environment.

2. ***Increase the level of collaboration with ESOH leaders.*** In the Army and throughout the DoD, a flexible, proactive, life cycle risk-based strategy can be implemented to reduce current and future vulnerabilities. To accomplish this, the Army may elect to leverage their resources to effectively achieve the DoD's pledge to coordinate nanotechnology research programs with the Services and Federal agencies (e.g., the Coordinating Agencies for the EHS PCA) and avoid duplication of RDT&E efforts.[118] This may include a written agreement, e.g., a memorandum of understanding, developed with NNI EHS PCA Coordinating Agencies to ensure appointed Army personnel are empowered to coordinate and collaborate with these agencies. This type of collaboration will build upon existing relationships DoD facilities maintain with the NIOSH Nanotechnology Field Research Team. For example, Edwards Air Force Base, Wright-Patterson Air Force Base, Picatinny Arsenal, and the U.S. Army Engineer Research and Development Center ERDC in Vicksburg, MS have teamed with the NIOSH Field Team to voluntarily participate in onsite occupational health assessments.[119] An expanded relationship with NIOSH, or other Coordinating Agencies, will increase collaboration and place the Army, and the DoD, at the forefront of ESOH risk assessment and management.

3. ***Develop robust guidance for considering the ESOH life cycle risks of nanomaterials within the existing risk assessment and management frameworks.*** The DoD and Army system safety frameworks are effective at identifying and reducing or eliminating unacceptable risks from

[118] Department of Defense (2007)
[119] Personal communication with Mark Methner, NIOSH Nanotechnology Field Research Team, 14 May 2009.

known hazards. Since most nanomaterials have not been identified as hazardous, users of these frameworks may not identify them as a material of concern. Robust guidance is needed that assists Army ESOH professionals, nanotechnology developers and users, Science and Technology Managers, and Program Managers in the identification of potential nanomaterial ESOH risks in concert with life cycle impacts, scientific uncertainties, control strategies, stakeholders, and effective risk communication methods. This guidance will supplement and work in conjunction with existing Army risk frameworks, such as CRM, to more effectively consider the life cycle risks and impacts of novel materials for which little or no hazard information is available (e.g., nanomaterials) and compare the tradeoffs between options.

The Army has experience integrating frameworks and evaluating tradeoffs between risk and impact options. For example, Field Manual 100-14 applies CRM to the military decision making process and Army training management system in tactical and garrison environments. In addition, two AEPI projects, "Sustainability Analysis Tools for Strategic Planning and Decision-Making" and "Strategic Technology Opportunity Analysis for Driving Sustainable Innovation and Investment," provided frameworks for identifying technologies and evaluating their ability to support Army sustainability. The principles developed in these and other analytical frameworks should be considered in the evaluation of ESOH risks in concert with other life cycle impact and in the evaluation of tradeoffs between options.

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APPENDIX A
DoD Memorandum on Engineered Nanomaterials

THE UNDER SECRETARY OF DEFENSE
3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION, TECHNOLOGY AND LOGISTICS

MAY 13 2008

MEMORANDUM FOR: SEE DISTRIBUTION

SUBJECT: Environment, Safety and Occupational Health (ESOH) Risks from Engineered Nanomaterials

This memorandum reinforces responsibilities and provides information for managing ESOH risks of engineered nanomaterials in DoD research, acquisition, operations, and support. The Department is committed to realizing mission benefits from engineered nanomaterials. At the nanoscale (the size range between approximately 1 and 100 nanometers), material properties may enable new mission applications but may also present ESOH risks that are different than those for comparable material at a larger scale. A few studies have indicated potential ESOH risks in very specific nanomaterial systems and conditions, but they do not provide sufficient information at this time to direct risk controls or to assign risk uniformly.

Science and technology (S&T) managers, acquisition program managers (PMs), and ESOH professionals should exercise due diligence in meeting their responsibilities to protect the health and safety of workers and the public, and to protect the environment. S&T managers should support ESOH risk research to close information gaps in developmental efforts using nanomaterials. As with any materials technology, PMs must ensure ESOH hazards are identified and the associated risks managed pursuant to DoDI 5000.2, Military Standard 882D, and other DoD policy requirements. Appropriate acquisition documentation should reflect ESOH hazard and risk assessments in both technology and system development efforts that involve engineered nanomaterials. DoD developers and users shall follow the procedures in DoDI 6050.05 for storing and using engineered nanomaterials in each workplace.

ESOH professionals will be challenged by the rapidly evolving nature of nanomaterials, especially while no current set of standards exists to fully evaluate their ESOH risks. Nevertheless, they shall maintain current knowledge of ESOH risks for engineered nanomaterials and provide S&T managers, PMs, and users with ESOH risk management options required by DoDI 6055.5. As information relevant to emerging nanomaterials risk science and policy issues becomes available, it will be posted at the Defense ESOH Information Exchange site (www.DENIX/osd.mil under the MERIT working group). A list of ESOH risk information resources is attached. My point of contact is Ms. Shannon Cunniff, Director, Emerging Contaminants, at shannon.cunniff@osd.mil.

Jack Bell, Acting 5-13-08
John J. Young, Jr.

Attachment:
As stated

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ASSISTANT TO THE SECRETARY OF DEFENSE NUCLEAR & CHEMICAL & BIOLOGICAL DEFENSE PROGRAM
DIRECTOR, MISSILE DEFENSE AGENCY
ASSISTANT SECRETARY OF THE ARMY (INSTALLATIONS & ENVIRONMENT)
ASSISTANT SECRETARY OF THE NAVY (INSTALLATIONS & ENVIRONMENT)
ASSISTANT SECRETARY OF THE AIR FORCE (INSTALLATIONS, ENVIRONMENT & LOGISTICS)
DIRECTOR, DEFENSE TEST RESOURCE MANAGEMENT CENTER
DEPUTY GENERAL COUNSEL (ENVIRONMENT AND INSTALLATIONS)

NANOMATERIALS ESOH RISK INFORMATION RESOURCES

Defense Information Resources:

Defense Environmental Information Exchange (DENIX):

https://www.denix.osd.mil/denix/Public/Library/MERIT/merit.html

Other Federal Government Information Resources

Department of Energy (DOE):

http://www.sc.doe.gov/bes/DOE_NSRC_Approach_to_Nanomaterial_ESH.pdf

Environmental Protection Agency (EPA):

http://es.epa.gov/ncer/nano/

National Institute for Occupational Safety and Health (NIOSH):

http://www.cdc.gov/niosh/topics/nanotech/default.html

National Nanotechnology Initiative (NNI):

http://www.nano.gov/html/society/EHS.html

Office of Science and Technology Policy and Council on Environmental Quality Principles for Nanotechnology Environmental, Health, and Safety Oversight:
http://www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf